Abt Associates Inc.

Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services

Draft of Proposed Recommendations

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Quality Standards for Suppliers of DMEPOS

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The Product-Specific standards development process is a continuing work in progress and will be completed by January 2006. We request advice from the Program Advisory Oversight Committee (PAOC) to assist us in the completion of the quality standards to meet the unique needs of the DMEPOS industry and beneficiaries.

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Expert References of Best Practices

Transtracheal Systems (Respiratory)
109 Inverness Drive East, Suite J
Englewood, Colorado 80112-5105

American Association for Respiratory Care (AARC) Clinical Practice Guidelines
http://www.rcjournal.com/online_resources/cpgs/cpg_index.asp

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Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services

Introduction

Section 1834(a)(20) of the Social Security Act added by section 302(a)(1) of the Medicare Modernization Act 2003 requires suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and other items and services to comply with quality standards established by the Secretary in order to furnish any item or service for which payment is made under Medicare Part B, and to receive and retain a supplier billing number used to submit claims for reimbursement for any such item or service for which payment may be made under Medicare. Medicare defines a supplier as a physician, or an entity other than a provider that furnishes health care services under Medicare. For purposes of meeting the intent of this statute, suppliers of DMEPOS are defined as entities that furnish health care equipment and related services to beneficiaries under Medicare Part B. The Medicare Part B payment for DMEPOS is limited to items and supplies used in or delivered to the beneficiary's home. The supplier shall have an active supplier billing number to process claims and receive Medicare payment for these services.

Section 1834(a)(20)(B) of the Act requires the Secretary to designate and approve one or more independent accreditation organizations to apply the quality standards to suppliers of DMEPOS and other items and services. Therefore, suppliers of DMEPOS shall be accredited by a CMS approved accreditation organization to receive Medicare payments for services rendered. The accreditation survey process will emphasize related processes and outcomes of services validated through unannounced onsite visits to each supplier location and during interviews with beneficiaries. Further detail on the selection process for accreditation organizations will be outlined in rulemaking.

In considering an approach for the quality standards development process, we consulted with DMEPOS suppliers, physicians, and homecare associations. We determined that effective DMEPOS services involve ongoing communication between the supplier and the treating physician and other healthcare team members to ensure that appropriate equipment and supplies are supplied to meet the medical needs of the beneficiaries. Because suppliers specialize in DMEPOS products and services, and because of the complexity of clinical monitoring required for some areas of DMEPOS, we developed two distinct groups of standards: 1) business quality standards that apply to all Medicare suppliers regardless of specialization, and 2) sets of quality standards applicable to a specific product or category of products. The product-specific quality standards are additional requirements that shall be met when supplying those particular products. Thus, for accreditation purposes, the supplier will be accredited only when they meet business quality standards as well as those quality standards that apply to the specific products for which the supplier has applied through Medicare to market and distribute.

Section 1: Supplier Business Quality Standards

Administration

The supplier shall govern its business in a manner that enables it to use its resources effectively and efficiently to procure appropriate quality equipment and supplies, and to deliver quality services to beneficiaries in compliance with Federal, State and local laws.

1. The supplier shall have a governing body, or designated persons performing comparable functions, with the legal authority, responsibility, and accountability for establishing and implementing policies and procedures regarding the organization's management and operation. The policies and procedures shall be reviewed and revised annually to ensure that they meet the Centers for Medicare and Medicaid Services (CMS) regulations, policies, and accreditation organization requirements.

2. The supplier shall provide only those equipment, supplies, and services to Medicare beneficiaries, which it disclosed on the CMS-855S. All licenses, certificates, and permits to operate shall be displayed in a public place and be accessible upon request to government officials or others acting on behalf of the government.

3. Procurement and testing of quality durable medical equipment (DME) and supplies. The supplier shall develop and implement policies and procedures that:

- Describe methods for ensuring manufacturers provide evidence of how equipment is tested to meet the standards for ensuring product quality and safety. At a minimum, the procured equipment and supplies shall be from manufacturers whose products meet the applicable Food and Drug Administration (FDA) medical device effectiveness and safety requirements, American National Standards Institute (ANSI) standards, Rehabilitation Engineering and Assistive Technology Society (RESNA) standards, and International Organization for Standardization (ISO) of quality system standards as applicable; and

- Describe the process for and maintain documentation of the product's features, instructions, and warranties for each type of non-custom fabricated equipment.

4. Delivery of quality services to beneficiaries. The supplier shall be responsible for delivering Medicare covered items to beneficiaries, and shall maintain proof of such delivery. The supplier shall develop and implement policies and procedures that:

- Define the scope and provision of supplier services, beneficiary eligibility requirements, how services are coordinated with the treating physician and healthcare team, and business and emergency operating hours. The supplier shall maintain business hours at its location for beneficiaries for a minimum of 40 hours a week. Theses hours shall be posted at the business location. Suppliers shall have staff available for telephone customer service during posted business hours and after-hours emergency service;

- Ensures that mail order services are not used for the initial delivery, set-up, and beneficiary education/training for certain DME equipment and supplies. For replacement mail-order deliveries, the DME supplier shall ensure that products and supplies are consistent with the treating physician's order, meet the product specifications as prescribed by the treating physician, and that qualified staff are available to respond to beneficiary concerns and needs;

- Ensures the acceptance of returns from beneficiaries of substandard equipment (i.e., less than full quality for the particular item or unsuitable items that are inappropriate for the beneficiary at the time it was fitted and rented or sold);

- Describe the procedures and timeframes for DME rental, delivery, pick-up, maintenance, storage, repairs, replacement, and warranties of equipment and supplies, the associated costs, and discharge of beneficiary from services;

- Ensures that in a medical emergency, the DMEPOS supplier staff refers the beneficiary directly to his or her physician or a "911" operator;

- Ensures that DME suppliers maintain a list of all equipment and supplies and how they are provided to the beneficiary (new or in used condition, offered for purchase or rental) and indicate whether each item can be covered by Medicare or Medicaid; and

- Provides the beneficiary with a toll free telephone number or other national access numbers for all applicable equipment to assist the beneficiary in accessing support from the supplier or manufacturer when needed.

5. The supplier shall:

    - Maintain compliance with Federal, State, and local laws;
    - Comply with the supplier enrollment standards at 42 CFR 424.57; and
    - Comply with the disclosure of ownership and control information requirements at 42 CFR 420.201, 42 CFR 420.204, 42 CFR 420.205, and 42 CFR 420.206 including:

        a) Provide written notice to CMS, the National Supplier Clearinghouse (NSC), and its accreditation organization at the time of change in ownership, if a change occurs in:

            i) The officers, directors, agents, or management; or

            ii) The corporation, association, or other company responsible for the management of the organizations;

        b) The notice shall include the identity of each new individual or company; and

        c) Each supplier location, whether owned or subcontracted, shall meet the quality standards and be accredited.

- Comply with other Health and Human Services (HHS) regulations including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin under federal regulation (45 CFR part 80); nondiscrimination on the basis of handicap under federal regulation (45 CFR part 84); and nondiscrimination on the basis of age under federal regulation (45 CFR part 91).

6. The supplier shall develop and implement a compliance plan that implements policies and procedures to control program fraud, waste, and abuse, including at a minimum the following elements:

- Written policies, procedures, and standards of conduct that articulate the organization's compliance with all applicable Federal and State standards;

- The designation of a compliance officer and compliance committee (or individuals who will perform comparable functions) accountable to senior management/ownership of the company;

- Effective training and education for the organization's employees, contractors, agents and directors (as applicable) regarding compliance with the organizations' standards and policies;

- Procedures for applying consistent enforcement of standards, such as by applying disciplinary guidelines; and

- Procedures for effective internal monitoring and auditing.

Financial Management

The supplier shall develop and implement financial management policies, procedures, and practices to ensure accurate accounting, business integrity, and accountability.

The supplier shall use an accounting system to track and manage revenues and expenses on an ongoing basis and to provide evidence of the following to CMS, the accreditation organizations, and others acting on behalf of the government upon request:

1. A financial management plan that includes:

a) An annual operating budget according to generally accepted accounting principles (GAAP);
b) Data sheets of annual projected and actual income;
c) Data sheets of annual expenses and cash flow;
d) Balance sheets;
e) Statements of changes in net position; and
f) Invoices and receipts related to each beneficiary's equipment, supplies, and services.

2. Financial statements that are accounted for, recorded, and audited by accounting personnel to ensure financial propriety.

3. Notification to CMS and the accreditation organizations of potential adverse financial operations. The supplier shall maintain adequate financial resources to ensure that the supplier can meet its financial obligations for each quarter. The supplier shall advise CMS and the supplier's accrediting agency when it first becomes aware of adverse financial conditions which could potentially result in delayed payments to its manufacturers/suppliers or bankruptcy.

Human Resource Management

The supplier shall develop and implement policies and procedures that specify personnel qualifications, training, experience, and continuing education requirements consistent with the specialized equipment, supplies, and services it provides to beneficiaries.

1. The supplier shall obtain criminal background checks on all employees in compliance with State and Federal laws.

2. The supplier shall have sufficient full-time and/or part-time personnel to provide the services to meet the demands of the beneficiaries it serves. Professional personnel shall be licensed, certified, or registered in accordance with applicable State and Federal laws and policies. The professional personnel shall be knowledgeable in the equipment and supplies provided by the supplier to meet the medical needs of the beneficiaries.

3. The supplier shall maintain documentation of annual verification of licensure, registrations, certifications, and of any other qualifications and competencies needed for all of its personnel and management who are involved in providing beneficiary services.

4. The supplier shall have and implement an assessment program to evaluate and document staff competence in areas related to its product specialization and beneficiary services. The supplier shall have documentation proving that each staff member is current and in good standing with his/her applicable credentialing/licensure organization(s).

5. The supplier shall inform and train all management and staff regarding their responsibilities, the types of services provided by the supplier, the organization's policies and procedures, and any other pertinent information.

6. The supplier shall prohibit employees with a communicable disease or infected skin lesions from entering the home of beneficiaries, if contact with the premises, equipment and/or beneficiary could transmit the disease. The supplier shall maintain current documentation regarding the results of employees' tuberculosis screening and Hepatitis B vaccination or declination, as described in applicable Occupational Safety and Health Administration (OSHA) requirements and Centers for Disease Control (CDC) guidelines.

7. The supplier shall ensure that all drivers who deliver DMEPOS as part of Medicare Part B services to beneficiaries in skilled nursing facilities, hospitals, or any other entities have a valid driver's license.

8. The supplier shall ensure that personnel are employed and assigned responsibilities commensurate with their education and experience. Credentialed individuals shall have documented knowledge and demonstrated competencies to:

- Inspect, deliver, and setup the prescribed equipment (does not apply to O&P facilities);
- Evaluate, adjust, and monitor the prescribed equipment;
- Instruct the beneficiary and caregiver in the proper use, operation, maintenance, repair of, troubleshooting, and reporting of problems for equipment provided; and
- Communicate results of services to the treating physician and other health care team members.

Beneficiary Services

1. The supplier shall process and document physician orders in accordance with the instructions in the CMS Program Integrity Manual, Chapter 5. The supplier shall document communication with physicians and other referral sources to include:

- A review of the beneficiary's prescription/referral, and consultation with the physician/referral source if the original prescription and/or treatment plan requires clarification or modification; and
- Consultation as necessary with other healthcare professionals and practitioners about the beneficiary's condition to formulate a service plan. The supplier shall document all findings and actions taken, and communicate these with the appropriate healthcare professionals (e.g., referral sources, colleagues, supervisor) to ensure the beneficiary's status is updated and current.

2. The supplier shall ensure the following when providing access to equipment, supplies, services, and information for beneficiaries:

- In advertisements, websites, and ordering instructions access to services is clearly explained;
- All DME and other items and services distributed to beneficiaries shall include clear instructions on use, maintenance, potential hazards, as well as how to report any failures and malfunctions;
- There is a policy and process in place to remove recalled products from distribution, which includes parameters on how to notify beneficiaries and also provides information on how to return or dispose of the product;
- For DME suppliers, there are defined and guaranteed estimates for the time needed to ship items (estimated duration from the time supplier receives an order to the time an order is shipped) and these are disclosed to the beneficiary;

- Receipt of all DMEPOS and services will be confirmed with the beneficiary; and

- For DME, suppliers shall have identification stickers on capped-rental equipment showing the company's name, address, and telephone number.

3. The supplier shall ensure coordination of services with the treating physician and other healthcare team members, and shall:

- Review all physician orders to ensure a clear understanding of the equipment and supplies requested and shall use this information in the delivery planning process;

- Give consideration to the beneficiary and/or caregiver's needs when scheduling the delivery and services of equipment and supplies;

- Consult with the treating physician and healthcare team to obtain pertinent beneficiary healthcare information that may have an impact on the medical use of the prescribed equipment:

    a) Diagnoses;
    b) Prognosis;
    c) Mental status;
    d) Functional limitations;
    e) Types of services and equipment required;
    f) Amount, frequency, and duration of treatments;
    g) Frequency of visits;
    h) Rehabilitation potential;
    i) Activities permitted;
    j) Nutritional requirements;
    k) Medications and treatments;
    l) Any safety measures to protect against injury;
    m) Instructions for timely discharge and/or referral; and
    n) Any other necessary information to ensure delivery of appropriate services.

4. The supplier shall develop and implement policies and procedures describing:

    a) The referral and acceptance process;
    b) How delivery of equipment and supplies are prioritized; and
    c) Staff response during emergencies, inclement weather, or any other emergent event that may disrupt services.

5. The supplier shall ensure that education and training is provided to the beneficiary on how to use Medicare covered items safely and effectively. This education and training shall be documented in the beneficiary's service plan, including identification of those who conducted the training. Evidence that the beneficiary or caregiver demonstrated their understanding of instructions shall be documented in the beneficiary's service plan.

Performance Management

The supplier shall develop and implement a performance management system that measures its effectiveness and efficiency in meeting organizational goals, compliance with its policies and procedures, as well as Federal, State, and local law requirements. The supplier should compare projected results to actual results, investigate any deviations from plans, evaluate individual staff performances, examine progress toward meeting stated organizational objectives, and implement corrective actions.

1. The supplier shall provide evidence of criteria selected, collected, monitored, evaluated, and the outcomes presented and actions taken. Performance criteria shall be measurable and verifiable, and include both quantitative and qualitative measures.

2. The supplier shall identify, monitor, and evaluate problems to determine root cause(s) including any adverse effects of equipment and supplies on beneficiaries.

3. The supplier shall respond to identified problems by developing, implementing, and monitoring strategies to improve quality of services and products.

4. The supplier shall implement procedures and a schedule to evaluate the effectiveness of utilized strategies.

5. The supplier shall conduct beneficiary satisfaction surveys and make the results available upon request and/or listed on their Internet website (if applicable). The supplier shall document and review on a quarterly basis a percentage of beneficiaries satisfied with services.

6. The supplier's performance management system shall utilize mechanisms to track trends and patterns related to the quality and outcomes of services, staff performance, beneficiary satisfaction, and financial stability of the organization. Examples of indicators that could be used to measure performance include but are not limited to:

- Reported as percentages:

    a) Accuracy of bills submitted to Medicare claim processing;
    b) Accuracy of bills submitted to beneficiaries;
    c) Beneficiary complaints received;
    d) Complaints resolved relative to all complaints received;
    e) Beneficiary complaints used to improve organizational performance;
    f) Responses to beneficiaries within 60 minutes of inquiry;
    g) Beneficiary calls with questions on equipment or supplies after provision of education/training;
    h) Distribution errors;
    i) Product returns relative to all products shipped;
    j) Product failures;
    k) Product recalls relative to all products shipped; and
    l) Staff that achieve competency in annual assessments.

- Reported as a whole number:

a) Number of adverse effects on beneficiaries as a result of inadequate or malfunctioning equipment, supplies, or services (e.g., actual or potential cause or contribution to a death or serious injury to the beneficiary as a result of malfunctioning equipment or services).

Equipment and Safety

The supplier shall develop and implement an equipment management program that ensures the prevention and control of safety risks and hazards both for its staff and for beneficiaries.

1. The supplier shall maintain a current and accurate inventory of all equipment, including the model, stock number, serial number, batch number, expiration date, and other information as applicable.

2. The DME supplier shall implement and maintain a system for tracking and monitoring the history of all equipment including an item's functions, failures, recalls, repairs, preventive maintenance, inspection, testing, and calibrations. There is a policy and process to report product failures to manufacturers and to appropriate agencies.

3. The DME supplier shall implement a system that describes how equipment will be serviced and routine follow-up procedures as well as emergency response procedures to prevent any interruption of services to the beneficiaries.

4. The supplier shall implement and maintain a process for honoring all warranties expressed and implied under applicable State laws. A supplier shall not charge the beneficiary or the Medicare program for the repair or replacement of items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in Federal regulation 42 CFR 414.229. The supplier shall maintain documentation that it has provided beneficiaries with information about Medicare supplied items covered under warranty, in the form of copies of all letters, logs, or signed notices.

5. The supplier shall conduct an environmental safety evaluation of a beneficiary's home including emergency power and notify the treating physician of potential or actual problems that may interfere with effective functioning or usage of the beneficiary's equipment (not applicable to O&P).

6. The supplier shall comply with all Federal, State and local laws and instructions regarding the safe transportation, storage, use, generation, and labeling of hazardous chemicals, materials, and waste (including cytotoxic medications, medical gases, blood and blood soaked items).

7. The supplier shall ensure there is adequate space within its facilities to support the delivery of beneficiary services as well as the separation of the manufacturing or storage of equipment from any hazardous materials and waste.

8. The supplier shall implement policies and procedures for the proper storage of parenteral and enteral nutrition therapy solutions and formulas, and medications with appropriate sanitation, temperature, light, moisture, ventilation, segregation, safety, and security (does not apply to O&P facilities).

9. The supplier shall implement policies and procedures regarding the preparation of medications and parenteral and enteral nutrition therapy solutions.

Beneficiary Rights and Ethics

The beneficiary has a right to self-determination as well as access to and communicates with persons and services of the supplier and healthcare team. A supplier shall protect and promote the rights of each beneficiary.

1. Prior to furnishing equipment, supplies, or services, the supplier shall inform the beneficiary of the following:

- The products and services that will be furnished;
- Any changes in the products or services;
- The schedule and procedures staff will follow to provide the products and services including the frequency of proposed visits;
- The rental versus purchase options available for equipment and supplies including associated costs (not applicable to O&P);
- Policies for after-hours and emergency coverage; and
- Telephone numbers for repair, emergencies, and customer service assistance.

2. The supplier shall respect the need of beneficiaries for confidentiality, privacy, and security. The supplier shall:

- Respect the beneficiary's right to personal privacy during rendering of services; and
- Respect the beneficiary's personal property and security during home visits.

3. The beneficiary has the right to request and to have the supplier resolve oral, written, and telephone complaints concerning the products and services provided by the supplier. The supplier shall develop and implement a complaint resolution system for identifying, responding to, and resolving complaints. The supplier shall maintain documentation of all written, oral, and telephone complaints it receives including:

- The name, address, and telephone number of the beneficiary;
- A summary of the complaint, including the date it was received, the name of the person making the complaint, the name of the person receiving the complaint, and a summary of the actions taken to resolve the complaint; and
- If an investigation was not conducted, the name of the person making the decision not to investigate and the reason for not doing so.

Information Management

The supplier shall develop and implement an information management system that ensures the accuracy, accessibility, confidentiality, and security of the organization's beneficiary's records, data, and dissemination of information. The supplier shall comply with the appropriate provisions and requirements of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable Federal and State requirements.

1. The supplier shall maintain records on each beneficiary that are complete, accurate, readily accessible, and systematically organized. A beneficiary's record shall include detailed descriptions of the specific products used by the beneficiary, customized designs of appliances and devices in use, pertinent medical history, relevant financial records, services provided including any follow-up, and evidence of any beneficiary education and training regarding DMEPOS and other items and services.

2. For suppliers that maintain records by computer instead of hard copy, the supplier shall develop and implement policies and procedures for electronic signatures and describe the attestation policy (ies) and other safeguards in force at each supplier location. In cases where such attestation is done on computer records, safeguards to prevent unauthorized access and reconstruction of information shall be in place including at minimum:

- Each computer or network shall have built-in safeguards to minimize the possibility of fraud;
- Each person responsible for an attestation has a unique individual identifier;
- The date and time is recorded from the computer's internal clock at the time of an entry, and date/time stamping is maintained to be accurate and current;
- An entry is not to be changed after it has been recorded;
- There is a backup system for all records and a process in place to provide for disaster recovery and business continuity; and
- Information systems and computer servers are secure.

3. The supplier shall implement safeguards to prevent loss, tampering, alteration, destruction, and unauthorized use or inadvertent disclosure of information and beneficiary records.

4. The supplier shall develop, implement, and enforce policies to prevent falsification of data and information.

5. The supplier shall develop and implement procedures governing the use and removal of records and the conditions for release of information.

6. The supplier shall implement a system to collect and aggregate administrative and beneficiary service data to ensure accuracy of interpretation, and to support decision-making, business operations, and performance improvement.

7. The supplier shall retain records of each beneficiary's equipment, supplies, education/training, and complaints for five years.

8. The supplier's marketing materials shall be clear, factual and not misrepresent the educational intent or Medicare costs and requirements for its products and supplies. The supplier's materials and websites (if applicable) provide:

- Documentation of accreditation, licensure and/or certification;
- Information for direct beneficiary access to a certified/licensed person, as applicable;
- A toll-free telephone number for direct beneficiary communication to DMEPOS service staff;
- The location and address of the DMEPOS supplier; and
- Forms for beneficiaries to download that are easy to access and use.

Section 2: Appendices for Supplier Product-Specific Service Requirements

Appendix A: Supplier Product-Specific Service Requirements

DMEPOS suppliers are required to be knowledgeable and competent in the inspection, delivery/set-up, beneficiary education/training, and follow-up for the equipment, supplies and services they provide to beneficiaries. The treating physician has the responsibility for all medical decisions and treatment plan regarding the medical use of the equipment and supplies and monitoring of the beneficiaries health status. To ensure consistency in each DMEPOS supplier's quality of services to beneficiaries, a supplier shall implement additional product-specific requirements for items that it provides.

The following general standards apply to all categories of equipment and supplies provided under Medicare Part B services.

Inspection and Preparation

The supplier shall ensure that the equipment is safe and fully functional, and adjust, repair, or replace parts if the condition of a product is below factory new-equivalent performance, or defects would render equipment unsafe. If adjustment, repair, or replacement of parts is not feasible or not sufficient to make the equipment safe and functional, the equipment shall be replaced.

Intake

The supplier shall:

- Obtain a written prescription from the Medicare beneficiary's treating physician for the equipment;
- Consult with the treating physician as needed, to confirm the prescription and to recommend any changes or refinements to the prescribed regimen; and
- Assure that the prescribed equipment is appropriate for the medical needs of the beneficiary.
- Ensure changes in equipment and services are accepted by the treating physician via either verbal or written communication. The supplier shall ensure that only individuals who are authorized under applicable State laws and regulations accept verbal orders. A written order from the treating physician shall be on file upon billing for delivered services.

Service Plan

The supplier shall:

- Develop and implement a service plan for each beneficiary based on the treating physician's plan of care; and

- Periodically review the service plan and incorporate any necessary revisions. The treating physician shall be contacted to discuss:
    - Changes in the beneficiary's clinical condition;
    - Proposed changes in the service plan that affect the prescribed equipment or services; and
    - Identification of new beneficiary problems and needs or recurrence of previously resolved problems and needs.

Equipment Management

The supplier shall:

- Inspect the equipment to ensure that all necessary components are present;
- Check that the equipment is consistent with the treating physician's prescription and any other criteria for use; and
- Adjust, repair, or replace all components to ensure that they do not pose a hazard or usage problem for the beneficiary.

Delivery and Setup

The supplier shall ensure the equipment is properly delivered, setup and fully functional.

The supplier shall:

- Obtain physician orders for all necessary equipment, supplies, and accessories;
- Deliver and set up, or coordinate set up with a clinician or another provider, all equipment and supplies in a timely manner as agreed upon by the beneficiary and/or caregiver and supplier;
- Provide all supplies necessary to operate the equipment and that are needed along with the equipment;
- Ensure that instructions on the operation, safety, maintenance, repair, and replacement are provided to the beneficiary along with any warnings about use, and any additional manufacturer's instructions;
- Ensure that all equipment and supplies are clean and sterile as indicated;
- Take reasonable measures to present instructions and information to the beneficiary and/or caregiver in clear, understandable language;
- Supply any follow-up service;
- Assess and reassess parameters for the specific equipment and/or any physician guidelines.

- Perform or arrange for any needed maintenance and repairs or replacement;
- Have access to replacement parts, either through maintaining inventory or arrangements with other suppliers;
- Provide a written estimate to the beneficiary of the cost and time required for any repair work;
- Provide, or arrange for, loaner equipment comparable to the original equipment for any repair period;
- Establish an adequate means for the beneficiary to communicate needs and desires and to obtain help in case of emergency;
- Advise the beneficiary on how to communicate their needs and concerns and to summon help in case of an emergency;
- Document the beneficiary's use of all equipment for home use;
- Provide a specific written statement of warranty on the equipment provided, including commercial warranties on manufactured equipment or components, and any dealer warranties on adapted or custom-fabricated items; and
- Provide, or advise the beneficiary about how to access information, equipment, and supplies to maintain Universal Precautions.

Condition of the Home

The supplier shall:

- Assess the beneficiary's home for safety concerns related to the use of the equipment and supplies provided; and
- Evaluate the adequacy of electricity and/or water that is needed to safely operate the equipment provided. Notify the treating physician immediately if there are health-related or other problems that impose a threat to the safe operation and function of the equipment.

Training/Instruction to Beneficiary and Caregiver

The supplier shall ensure that the beneficiary and/or caregiver(s) receive all necessary instructions and training related to the use and maintenance of the equipment.

The supplier shall:

- Provide, or coordinate the provision of, appropriate instruction and information related to the set-up, features, routine use, troubleshooting, safety, cleaning, and maintenance of the equipment and supplies provided. Such instruction may be in written, video, or electronic format supplemented with oral instructions;

- Document in the service plan that such instructions were provided;
- Inform the beneficiary and/or caregiver how to contact the supplier for routine and after-hours equipment problems;
- Provide information and/or instruction about infection control issues related to use of the equipment and/or supplies; and
- Ensure that the beneficiary and/or caregiver know when and how to obtain help if a medical emergency arises.

The supplier shall provide to the beneficiary/ caregiver and/or review:

- A copy of the user instruction manual and warranty;
- The beneficiary's rights and responsibilities as a consumer;
- The supplier's privacy practices;
- The process to communicate compliments and complaints or concerns; and
- Important telephone numbers for repair, emergencies, and customer service assistance.

Follow-up

The supplier shall provide beneficiary follow-up services, consistent with the service(s) already provided, the beneficiary's diagnosis, and any recommendations from clinical referral sources. The supplier shall:

- Communicate with the treating physician or clinical team regarding outcomes of monitoring, maintenance, and operation of all equipment provided to the beneficiary;
- Periodically review the service plan with the treating physician or clinicians regarding the beneficiary's medical condition and the continued use and tolerance of the equipment and supplies; and
- Communicate any clinically significant beneficiary concerns, needs, and condition changes that affect the beneficiary's use of equipment and supplies to the treating physician within 24 hours of determination.

Appendix B: Oxygen and Oxygen Equipment

This standard refers to oxygen and oxygen equipment provided in the home setting. Oxygen equipment and supplies includes the following categories of equipment and supplies:

- Oxygen concentrator, reservoir, or high-pressure cylinder;
- Oxygen accessories and supplies; and
- Oxygen conserving devices.

The supplier shall provide qualified personnel for the delivery, set-up, beneficiary education, monitoring (home visit or telephone call based on the clinical condition of the beneficiary) and follow-up.

Inspection and Preparation

Intake

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Obtain a written prescription from the beneficiary's treating physician (based on the physician's face-to-face examination to determine medical need) who has prescribed the equipment. This shall be done before furnishing the oxygen equipment to the beneficiary; and
- Ensure that the prescribed equipment is consistent with the treating physician's written prescription.

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Defer to the treating physician for any changes in the details of the oxygen settings;
- Document any changes in the oxygen settings in the service plan record;
- Inspect, monitor, and service home oxygen equipment and/or supplies, per manufacturer guidelines;
- Have replacement equipment available and provide it for immediate use if a need arises;
- Be available for emergency services, 24 hours a day, 7 days a week, including holidays; and
- Respond within 60 minutes of receiving a service telephone call from the beneficiary or caregiver, and provide any in-home services as needed.

Delivery and Set-up

See General Product-Specific Service Requirements

Condition of the Home

See General Product-Specific Service Requirements

Condition of the Equipment

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Ensure that the following oxygen equipment meets minimum standards and has the following specific features.

Oxygen Concentrator:

- Has a working alarm to alert the beneficiary to a power outage or mechanical failure; and
- Is insulated to protect against electrical shock, consistent with applicable codes and standards.

Liquid Oxygen

- Includes a contents display that indicates the remaining volume of oxygen.

Oxygen Cylinder

- Is secured with a stand or an appropriate equivalent.

Portable Oxygen

- A stand-alone system or a complement to a stationary system that allows beneficiaries to ambulate within their homes.

Training/Instruction to Beneficiary and Caregiver

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary as follows:

Oxygen Equipment: Oxygen Concentrators

Equipment Usage

- Placing the unit in a well-ventilated area to prevent overheating and malfunction.
- Plugging equipment directly into a working grounded outlet.
- How to attach the cannula to the oxygen port on the unit.

- How to listen for the sound of the internal alarm setting when turning on the concentrator.

- How to set the oxygen flow at the prescribed level, the importance of using the prescribed level of oxygen, and the reasons for not changing the oxygen flow setting without the treating physician's approval.

- How to correctly place the oxygen delivery device (mask or cannula) and reasons for not using an oxygen mask with a concentrator on less than 4L of oxygen flow.

- How to recognize if oxygen is flowing through the cannula and identify normal operating sounds of the concentrator use; for example, as the compressor separates the oxygen from unneeded room air gases.

- How to check oxygen concentrator periodically to assure that it is delivering 85% oxygen or greater at 4L/min.

- The need to keep the concentrator at least 18 inches from drapes, sheets, bedspread, or anything else that may block air inlets.

- The need to have a backup source of oxygen in case of an electrical failure.

Special Procedures

If using a humidifier, instruct the beneficiary on how to:

- Remove the supply-tubing adapter;

- Secure the humidifier to the concentrator;

- Attach tubing to the humidifier output; and

- Ensure the humidifier "bubbles" once the unit is turned **on**. If "bubbling" does not occur, how to check the connections.

Maintenance

- How to clean the cabinet filters.

- How to wash a refillable humidifier. The beneficiary should use an alternate humidifier while cleaning the humidifier bottle.

- How to disassemble a humidifier, ensuring that the connector remains intact with the concentrator. Do not discard the connector because it helps hold the humidifier bottle or tubing to the concentrator.

Frequently replaced items

- Cannula or mask (twice a week).

- If using a humidifier:
    - if disposable, then the supplier shall replace it as needed but at least monthly; or
    - if refillable, then the beneficiary shall clean or refill with sterile or distilled water every 72 hours.

Infection control related to humidifiers

- Under normal circumstances, low-flow oxygen systems without humidifiers do not present a clinically significant infection risk and need not be replaced routinely.

- High-flow systems that employ heated humidifiers or aerosol generators, particularly when applied to individuals with artificial airways, may be a significant source of infection and should be cleaned and disinfected on a regular basis. These cleaning cycles should be documented in the service plan.

Oxygen Equipment: Liquid Oxygen Reservoirs

Equipment Usage

- How to select the proper and safest location for equipment in the home.

- How to fill the humidifier bottle with distilled water to the level indicated.

- How to attach humidifier bottle to the oxygen outlet on the liquid system by screwing humidifier bottle inlet to the oxygen outlet.

- How to attach oxygen tubing to humidifier bottle nipple.

- How to adjust the oxygen flow to the flow rate prescribed by the treating physician.

- How to adjust the nasal cannula or oxygen mask to fit properly on the face.

- How to check the humidifier bottle for bubbles as a steady flow of bubbles indicates proper oxygen flow.

- How to handle a liquid oxygen leakage safely. Liquid oxygen is extremely cold and can cause severe burns.

Special Procedures

When filling the Portable Unit:

- How to check the stationary system content gauge to ensure there is enough liquid oxygen.

- How to connect the stationary and portable units and fill the unit properly. Filling time will depend on the size of the portable unit and the temperature of the portable system. When the unit is full, there should be an alert sound and a fog venting from the stationary unit.

- How to remove the portable unit from the stationary unit, according to the manufacturer's instructions.

- How to respond if the portable unit does not easily release or is frozen to the stationary system.

Maintenance

- The need to ensure that the connections on the stationary and portable units are clean and dry before attempting to fill the stationary unit, to help avoid freezing.

- The need to contact the supplier before the stationary unit is completely empty. There is evaporation loss from the canisters when they are not in use. Only the liquid oxygen supplier should refill the liquid oxygen reservoir as needed.

- How to check liquid systems periodically to ensure adequate oxygen delivery.

Frequently Replaced Items

- The need to replace the nasal cannula or mask needs to be replaced approximately every two weeks.

- The need to replace the humidifier bottle approximately monthly.

- The need to replace oxygen tubing approximately every three months.

Oxygen Equipment: High-pressure Oxygen Cylinders

Equipment Usage

- How to select the proper and safest location for equipment in the home.

- Need to place the oxygen cylinder securely on a cart or stationary stand.

- How to attach and secure the regulator to the cylinder.

- How to attach tubing to the regulator port.

- How to start oxygen flow from the tank, and then open the valve on the regulator.

- How to identify any escape of oxygen, and what to do if oxygen is heard escaping.

- How to check the contents gauge.

Maintenance

- Need to replace the oxygen cannula once a week.

- How to wipe the tanks down with a damp cloth regularly to prevent dust and dirt from collecting.

- When and how to replace the 'washers' on the regulator should leaks occur (use only recommended washers).

Frequently replaced items

- Need to replace the oxygen cannula once a week.
- Regarding the oxygen cylinders:
  - How to check the contents indicator or pressure gauge to tell how much oxygen is left; and
  - Need to order oxygen from the supplier 2-3 days ahead or when tank reads one-quarter full.

Safety Review for Oxygen Cylinders

- Do not oil or lubricate the regulator or post valve assembly.
- How to bleed pressure from the tank when not in use.
- The need to store the cylinders upright in a cool, dry, well-ventilated area.
- Do not use an oxygen mask with a humidifier connected to the oxygen cylinder. This may cause severe backpressure.
- Do not use an O2 mask with flows below 4 liters/minute as this may cause carbon dioxide retention.

Oxygen Equipment: Portable Oxygen Systems

Equipment Usage

- How to select an appropriate transportation method for portable oxygen supply, based on size and weight of unit and the ability and strength of the beneficiary. The system would be either a carrying bag or a wheeled transport cart.
- Need to plan a 25% reserve margin of available oxygen supply when deciding on the amount of time spent outside of the home.

Maintenance

- Refer to the maintenance requirements for Liquid Oxygen or High-Pressure Oxygen Cylinders depending on the type of portable unit being used.

Safety Review for Portable Oxygen Systems

- Keep unit in an upright position.
- When traveling by car:

- Need to keep the car windows slightly open at all times for ventilation;
- Need to secure the portable unit with a seat belt or other restraint;
- Do not store unit in the trunk of the car; and
- Place signs regarding the utilization of oxygen in the car facing outward.

Note: Traveling by plane or long distances from the home requires approval of a physician and proper arrangements with transportation companies.

Oxygen Accessories: Nasal Cannula

Equipment Usage

- How to attach one end of the tubing to the oxygen source, place and position curved prongs in the nostrils, and attach tubing in place around the head; for example, by looping around ears or attaching to eyeglasses.

Maintenance

- Need to wash nasal prongs with soap and warm water twice a week.

Frequently replaced items

- Need to replace nasal cannula and tubing once a month or more often as needed.

Oxygen Accessories: Oxygen Mask and Face Tent

Equipment Usage

- How to attach mask to oxygen supply using the plastic tubing. The oxygen comes through the tube and fills the mask, which covers the nose and mouth.

- How to attach the face tent to the oxygen supply using the plastic tubing. The oxygen comes through the tube and fills the tent, which covers the nose and mouth

- Note that it is okay to breathe in and out of either the nose or mouth and still get oxygen.

- How to hold the mask in place by placing the elastic strap behind the ears.

Maintenance

- Need to clean the mask with soap and warm water, and rinse thoroughly.

Frequently replaced items

- Need to replace the mask once every 2-4 weeks.

Oxygen Accessories: Oxygen-conserving devices

Equipment Usage

- How to open the cylinder, attach the regulator, attach the cannula to the conserving device, and attach the conserving device tubing to the cylinder.
- How best to place the cylinder and conserving device in their cases.
- How to turn on the device and use continuous and pulse flow modes.

Maintenance

- How to clean and maintain the device periodically.
- Do not immerse in any liquid or subject the device to harsh conditions such as extremely high or low temperatures.

Frequently replaced items

- If a problem exists with the pulse flow, how to change to continuous flow on conserving device until the device can be replaced.
- Provide the beneficiary with contact information regarding changing the conserving device.

Safety Review with oxygen-conserving devices

- Do not use in conjunction with other oxygen accessories such as a humidifier or nebulizer.

Transtracheal Oxygen

Equipment Usage

- How to prepare for use, clean and rinse the skin around the catheter, lubricate catheter tip, remove the existing indwelling catheter from the tract opening, insert the clean catheter.
- How long to try inserting the catheter before stopping and calling the doctor.
- How to use the nasal cannula at the prescribed flow rate and reconnect the oxygen hose.
- Instruction should include the removal and reinsertion of a transtracheal oxygen catheter.

Note: The beneficiary should only remove and re-insert the catheter a maximum of 2 times per day. Removal and reinsertion requires a clean, second catheter. Nasal oxygen should be used when removing and reinserting the catheter.

Maintenance of a catheter left in place

- How often to clean the catheter.
- How to prepare for use, clean and rinse the skin around the catheter, disconnect and clean the catheter, reconnect the oxygen hose to the catheter, and wash and store the cleaning rod.

Maintenance of a catheter taken out of place or removed

- How to prepare for cleaning, and then clean, disinfect, rinse, and store the catheter.

General Catheter Maintenance

- How and where to store the clean catheter and cleaning rod.
- Advise not to soak the catheter in any disinfecting solution, boil the catheter, or place it in very hot water (no water hotter than 120 degrees Fahrenheit).
- Replace the catheter routinely every 90 days or immediately if it develops visible cracks, breaks, permanent kinks, or a foul odor.

Oxygen Accessories: Oxygen Hose

Note: The supplier shall ensure that the oxygen hose is the appropriate size for the beneficiary so that the lower segment should drape just a few inches off the floor.

Equipment Usage

- How to attach the suspender clip, where to run the hose, and how to connect the end of the hose into the catheter.
- How to connect the oxygen hose to the oxygen supply.
- How to ensure that all connections fit tightly and are secured; what to do if they are not.

Frequently Replaced Items

- Need to replace hose routinely every 90 days or immediately if it develops visible cracks, breaks, permanent kinks, or a foul odor.

Safety Review for Transtracheal Oxygen

- The catheter should never be out of the tract for more than a few minutes, or the tract may begin to close.
- Need to keep the catheter clean to ensure that it properly functions.
- What to do if the catheter is not working properly and when to notify the physician.

- What to do if the humidifier pop-off is making excessive noises.
- Need to not remove or insert the catheter while oxygen is flowing through it.
- Keep tract opening clean and dry. Do not use any antibiotic, ointment, or cream around the tract opening.
- Where and how to secure the oxygen hose.
- Need to not pull, twist, crush, or cut any part of a transtracheal system.

General Safety for Oxygen Equipment

The supplier shall ensure that the beneficiary is instructed in general safety precautions and the safe use of the Oxygen Equipment including:

- Need to stay at least six feet away from any open flame or heat source (candles, gas stove, etc.) when using an oxygen system. If cooking while using oxygen, the beneficiary needs to ensure that the oxygen system tubing will not touch the gas flame or electric burner.
- Do not store an oxygen system near any heat sources or open flames.
- Do not smoke or allow others to smoke in the same room as an oxygen system. Need to post "No Smoking" signs in the rooms where oxygen is kept and used.
- The beneficiary shall contact his or her treating physician and notify the supplier before changing the oxygen flow rate.
- The maximum length of oxygen tubing that can be used without diluting the concentration of oxygen.
- How to ensure that the oxygen supply tubing is not kinked or obstructed.
- Do not operate any electrical appliances (such as electric razors, hair dryers, electric blankets, etc.) near oxygen equipment.
- How to check that electrical equipment in the area near the oxygen is properly grounded.
- Need to have a functioning smoke detector and fire extinguisher in the home at all times.
- Need to keep the oxygen system away from flammable products, including aerosol cans or sprays, and including products like air fresheners and hair spray.
- How to keep the oxygen system clean and dust-free.

- Do not use cleaning products or other products containing grease or oils, petroleum jelly, alcohol or flammable liquids on or near an oxygen system. These substances can ignite oxygen.

- Use water-based products instead of petroleum-based products for nasal dryness or irritations.

- Store the oxygen system away from foot traffic, to avoid knocking it over.

- Avoid extension cords with medical equipment, or use an appropriate heavy gauge extension cord if absolutely necessary.

- Secure loose cords and extra tubing to avoid tripping over them when using an oxygen system.

- Secure floor mats and throw rugs to avoid tripping or falling when using an oxygen system.

- Ensure that doorways, hallways, and rooms can allow for passage while using a portable oxygen system.

- Keep oxygen equipment turned off when not in use.

- Consider oxygen as a medication and use it as ordered by the doctor.

Beneficiary should notify the following:

- Inform the local fire department that oxygen is being utilized in the home; and

- Inform the electric company that oxygen is being utilized in the home in case of a power outage, so beneficiary can be placed on a priority service restoration list.

- The beneficiary should post telephone numbers of each in plain sight, preferably in a room where the oxygen is used or stored.

Follow-up

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Provide the treating physician a periodic report.

- Visit no less often than every two weeks for the first month and as ordered by the treating physician afterwards. The supplier may conduct telephone calls to assess the beneficiary's concerns.

- Perform internal maintenance of all equipment. The supplier should document maintenance at regularly scheduled intervals.

- Check oxygen purity at each visit as per manufacturer's guidelines.

Appendix C: Home Invasive Mechanical Ventilation Therapy

This standard refers to beneficiaries ventilated by positive pressure via a tracheotomy tube in the home setting. Positive pressure ventilators apply positive pressure to the airways and lungs using an indwelling airway. When adults are being mechanically ventilated via a tube, the respiratory system becomes a closed system.

Verify that the discharging facility (for example, hospital or post-acute care facility) provided the beneficiary and/or lay caregiver with education and training on home ventilation therapy and management.

The supplier shall provide a licensed Respiratory Therapist to perform the delivery, set-up, beneficiary and/or caregiver education, and follow-up of services.

Inspection and Preparation

Intake

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Obtain a written prescription from the beneficiary's treating physician (based on a face-to-face examination to determine medical need) who has prescribed the invasive mechanical ventilation equipment and related medical supplies before furnishing the equipment to the beneficiary; and
- Ensure the physician prescribes the exact name and details all the components of the equipment required.

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Provide pertinent information to the treating physician to enable decisions regarding changes in invasive mechanical ventilation therapy.
- Document all changes in ventilator settings and maintenance services in the service plan record.
- Provide initial and monthly reports to the treating physician.
- Review laboratory tests results ordered by the treating physician and make adjustments to the ventilator settings as required.
- Visit daily for first 72 hours, weekly until beneficiary adjusts to therapy, no less than every two weeks afterward until the physician declares the beneficiary stable, and then as needed.

Equipment Management

See General Product-Specific Service Requirements

Delivery/Setup

In addition to General Product-Specific Service Requirements, the supplier shall:

- Ensure that any supplies associated with invasive mechanical ventilation therapy shall not be provided through a mail order service or through a distributor.
- Document ventilator-setting changes in service plan records.
- Confirm the presence of an ambu bag with mask.
- Provide and/or verify that an oxygen source exists to maintain the prescribed FiO2 concentration via the ventilator.

Condition of the Home

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Set up the equipment in a well-ventilated space away from open flames.

Condition of the Equipment

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Verify that the order includes the mode, tidal volume (TV), respiratory rate (RR), FiO2, (if appropriate: pressure limit, inspiratory time), and positive end-expiratory pressure (PEEP) setting
- Document the respiratory goals and objectives based on the treating physician's order and the short- and long-term goals for equipment.
- Record the parameters on the ventilator sheet and insert a copy of the completed form in the beneficiary's service plan.

Equipment and Supplies

In addition to the General Product-Specific Service Requirements, the supplier shall provide and verify appropriateness of all Invasive Mechanical Ventilation equipment and supplies provided, including:

- Invasive Mechanical Ventilator(s);
- Power Source;
- Alarms;
- Ventilator Circuit;
- Tracheotomy Tube;
- Humidification Systems;

- Suction Equipment;
- Oxygen if medically indicated; and
- Backup equipment and other related medical supplies.

Ventilator(s)

- Provide ventilators chosen for home care that are dependable, small, lightweight, and easy enough for the beneficiary or caregiver to operate.
- Ensure that the mechanical ventilator system permits beneficiary mobility, if indicated.
- Provide a backup ventilator for emergency safety purposes for:
    - Beneficiaries who cannot maintain spontaneous respirations for 4 or more consecutive hours;
    - Beneficiaries who live in an area where a replacement ventilator cannot be provided STAT (within 30 minutes); and
    - Portability (such as being mounted on a wheelchair).
- Perform a ventilator system check to verify and document:
    - Proper operation of the mechanical ventilator and connection to the beneficiary;
    - Activation of appropriate alarms;
    - Proper heating and humidification of inspired gas;
    - Inspired oxygen concentration matches the prescribed amount;
    - Ventilator settings comply with physician's order; and
    - Ventilator is turned on and the patient circuit is securely attached.
- Appropriate equipment should be available to perform the ventilator system check. Such equipment should include, but is not limited to:
    - Stethoscope;
    - Oxygen analyzer;
    - Ambu bag with mask;
    - Volume monitor (if applicable); and
    - Pressure monitor (if applicable).
- Oxygen equipment should include at least 6 hours of supply in the event of electrical failure or an emergency.

Power Source

- Ensure that an adequate power source is available to operate the ventilator consistent with beneficiary's medical needs. This may be supplied by one or more of the following methods:

- Alternating current (AC) is the primary power source for most long-term ventilators. Emergency AC backup power should be available.
- Direct current (DC) by external battery may be used to allow mobility and as an emergency power source.
- The ventilator's internal battery should be employed only for short-term, emergency use. It should not be used as a primary source of power.

Alarms

- Patient-disconnect and high-pressure alarms are essential. These should be set at patient-specific levels to minimize nuisance alarms.

- If patient disconnection is likely to produce a serious adverse effect, a remote alarm and a secondary alarm may be needed.

- If a secondary alarm is used it may be based on chest-wall impedance and cardiac activity, exhaled volume, end-tidal CO2, or pulse oximetry.

Ventilator Circuit

A ventilator circuit is a system of tubing that connects the beneficiary's airway to the ventilator itself. Most ventilator circuits are disposable, but reusable circuits are available. All ventilator circuits include inhalation tubing, exhalation tubing, ports for pressure detectors, a Y-connector, an elbow, a universal adapter, and a humidification device.

A supplier shall:

- Include an adapter for an in-line suction system or adapters for delivery of aerosol medications if medically necessary.

- Use a closed suction system to reduce prolonged intervals between, and frequency of, ventilator circuit changes.

- Provide extra ventilator circuits, as needed.

Tracheotomy Tube

- Secure all tubes to decrease tube movement and prevent accidental extubation (removal of the tube).

- Document the type and size of tube used and the method used to secure the tube and include in the beneficiary's service plan.

- Ensure that replacement tracheotomy tubes of appropriate size plus a tube one size smaller are available.

- If the outer cannula is inadvertently removed after a tract has formed, it can be replaced by inserting the obturator into the outer cannula and then inserting the

entire apparatus back into the tract. After the outer cannula is in place, remove the obturator and re-secure the outer cannula.

Humidification Systems

Humidification of inspired gas during mechanical ventilation is mandatory when an endotracheal or tracheotomy tube is present.

- Institute conditioning of inspired gases using either a Heat and Moisture Exchanger (HME) or a heated humidifier.
- Provide related equipment that may include, but is not limited to:
  - Humidification device (active or passive);
  - Heated Humidifier:
    - Used for beneficiaries requiring long-term mechanical ventilation (> 96 hours) or for those with contraindications for HME use;
    - Monitors inspired gas temperature;
    - Triggers alarm when the temperature falls outside a preset range;
    - Requires sterile water;
    - Operates actively to increase the heat and water vapor content of inspired gas;
    - Provides temperature probes; and
    - Use heated humidifiers that meet specifications of the American National Standards Institute (ANSI).
  - Heat and moisture exchanger (HME):
    - Better suited for short-term use (< or = 96 hours) and during transport;
    - Used during transport and to enhance mobility; and
    - Operates passively by storing heat and moisture from the beneficiary's exhaled gas and releasing it to the inhaled gas.
  - Bursting-bubble cascade-type humidifiers.
- Check humidifier performance specifications to assure adequate heating and humidification during expected peak inspiratory flow rate and minute ventilation delivered by the mechanical ventilator.
- Inspect the humidification device visually during the ventilator system check and remove condensate from the patient circuit as necessary.
- Inspect HMEs and replace if secretions have contaminated the insert or filter.
- The following variables should be recorded during inspection of humidification equipment:
  - Humidifier setting (temperature setting or numeric dial setting or both);
  - Inspired gas temperature. If using a heated humidifier, temperature should be monitored as near the beneficiary's airway opening as possible;

- Specific temperatures may vary with beneficiary condition, but the inspiratory gas should not exceed 37°C at the airway threshold; and
- Alarm settings (if applicable). High temperature alarm should be set no higher than 37°C, and the low temperature alarm should be set no lower than 30°C.

- Use of heat moisture exchangers (HME) is encouraged. Consider efficacy based on beneficiary's secretion volume and consistency.

Suction Equipment

- Options include bedside and portable machines.
- The tubes shall be kept clean, although they do not normally need to be sterilized.
- Equipment and supplies may include, but are not limited to:
  - Electrically powered aspirator with a calibrated, adjustable regulator and collection bottle with overflow protection;
  - A battery-powered aspirator may be needed for the beneficiary who leaves the home or who lives in an environment subject to frequent power failures;
  - Suction catheters, sized appropriately. Open suction systems are used most often;
  - Clean or sterile gloves as indicated; barrier protection when active infection is present or suspected;
  - Manual resuscitator when hyperinflation is medically indicated;
  - Oxygen source when preoxygenation is medically indicated;
  - Sterile normal saline for instillation when medically indicated;
  - Oral suction device (e.g., tonsil tip);
  - Sterile distilled and/or recently boiled water and cleaning solution; and
  - Tap water that has been boiled, stored in a closed, clean container, and used within 24 hours of boiling to flush the catheter. (Water directly from the tap should not be used because of the possibility of contamination)

Other Equipment and Supplies

- Cleaning equipment for the tracheotomy.
- Self-inflating resuscitation bag with tracheotomy attachments and appropriately sized mask.
- Gauze and tape for suction machines/tubing.
- Oxygen as medically indicated.
- Additional tracheotomy tubing.

Training/Instruction to Beneficiary and Caregiver

In addition to General Product-Specific Service Requirements, the supplier shall:

- Instruct caregivers about routine tracheotomy care and emergency replacement should the tracheotomy tube become dislodged or occluded; and

- Provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

Ventilators

- Instruct the lay caregiver on the operation of the ventilator.

- Teach beneficiary and/or caregiver how to assess and respond overtime to invasive mechanical ventilation.

- Inform lay caregiver of possible risks related to invasive mechanical ventilation, and how to respond to them.

- Provide emergency instructions in case of equipment-related complications including:

    - Power failure;
    - Accidental decannulation (tube comes out);
    - Other need for tracheotomy tube replacement;
    - Other unexpected events, such as medical deterioration of the beneficiary;
    - Failure of the ventilator or other equipment or supplies;
    - Inadequate warming and humidification of inspired gases;
    - Inadvertent changes in ventilator settings; and
    - Accidental disconnection from ventilator.
- Instruct the beneficiary to contact the supplier if the ventilator stops working or the beneficiary and/or caregiver needs to review a procedure or has questions.

- Document the ventilator's electrical and functional testing.

- Instruct caregivers to monitor:

    - Ventilator settings:
        - Peak pressures;
        - Preset tidal volume;
        - Frequency of ventilator breaths;
        - Verification of oxygen concentration setting;
        - Amount of oxygen available for supplying ventilator; and
        - PEEP level (if applicable).
    - Appropriate humidification of inspired gases:

        - Temperature of inspired gases (if applicable).
        - Heat and moisture exchanger function.
    - Equipment function:
        - Appropriate configuration of ventilator circuit;
        - Alarm function;
        - Cleanliness of filter(s), according to manufacturer's guidelines;
        - Battery power level(s), both internal and external;
        - Overall condition of all equipment; and
        - Self-inflating manual resuscitator cleanliness and function.
    - Oxygen saturation by pulse oximetry if such monitoring has been prescribed.
- Care should be taken to avoid breaking the ventilator circuit, which could contaminate the interior of the circuit.

- Other issues related to the technical aspects of mechanical ventilation may be important in relation to ventilator-associated pneumonia (VAP). Medication nebulizers can be a source of contamination that could lead to VAP. Accordingly, care should be taken with nebulizers to avoid contamination of the ventilator circuit and the patient's respiratory tract.

- Frequency of ventilation (and the beneficiary's ventilator-free time) depends on the patient's physiologic needs and is determined in consultation with the treating physician.

- How to keep the mechanical ventilator and related equipment clean/disinfected per manufacturer's guidelines.

Power Source

- Instruct the beneficiary on what to do if power is lost:

    - The ventilator has an internal battery that will power the unit for about 30 minutes.
    - An external battery should be available to power the ventilator in the event that power resumption is delayed or the beneficiary leaves the home. External batteries vary in amount of power available, depending on their size and age.
- Instruct the beneficiary that if the ventilator is portable and can be taken outside, it should be fitted with an appropriate external battery.

Humidification

- Inform beneficiary and caregivers of potential hazards and complication including:

    - Heated Humidifiers:
        - Potential for electrical shock;
        - Hyperthermia;
        - Thermal injury to the airway;

        - Burns to the beneficiary and tubing meltdown if heated-wire circuits are covered or electrical current/voltage is incompatible with the humidifier;
        - Potential for burns to caregivers from hot metal;
        - Inadvertent overfilling resulting in unintentional tracheal lavage; heated reservoir humidifiers;
        - When disconnected from the beneficiary, some ventilators generate a high flow through the patient circuit that may aerosolize contaminated condensate, putting both the patient and caregiver at risk for nosocomial infection;
        - Inadvertent tracheal lavage from pooled condensate in patient circuit;
        - Elevated airway pressures due to pooled condensation; and
        - Patient-ventilator dysynchrony and improper ventilator performance due to pooled condensation in the circuit.
    - HME:
        - Possible hypoventilation due to increased dead space; and
        - Ineffective low-pressure alarm during disconnection due to resistance through HME.
    - Heated Humidifiers or HME:
        - Hypoventilation and/or alveolar gas trapping due to mucus plugging of airways;
        - How inadequate hydration may contribute to impaction of mucus secretions;
        - Potential for hypothermia;
        - Possible increased resistive work of breathing due to mucus plugging of airways; and
        - Possible increased resistive work of breathing through the humidifier.
- Demonstrate method for filling the humidifier.

- Explain issues related to the use of passive humidifiers (resistance, dead space volume, airway occlusion risk).

- Instruct caregivers in how to:

    - Assess beneficiary response to humidification;
    - Recognize an adverse response to humidification;
    - Appropriately respond to adverse events; and
    - Recommend modifications in humidification techniques as needed.

- Inform beneficiary and/or caregiver that reusable heated humidifiers should be treated with high-level disinfection.

- Need to use clean technique and sterile water when filling the water reservoir.

- When using a closed, automatic feed system, the unused portion of water in the water feed reservoir remains sterile and need not be discarded when the patient circuit is changed.

- Because it is infectious waste, condensate should never be drained back into the humidifier reservoir.

- Passive humidifiers do not need to be changed daily for reasons of infection control or technical performance. They can be safely used for at least 48 hours, and with some patients, devices may be usable for up to 1 week.

Suction Equipment

- How to operate the suctioning equipment.

- How to suction the patient (with or without an artificial airway) including nasal, oropharyngeal, and endotracheal suctioning.

- How to determine frequency of suctioning.

- How to do preoxygenation and/or hyperinflation when indicated, including using a resuscitation bag with supplemental oxygen.

- How to use resuscitation bags and manual hyperventilation techniques. Improper or imprecise use of resuscitation bags for hyperinflation can cause lung injury and respiratory alkalosis.

- Limit instillation of normal saline solution to only when specifically medically indicated (for example, to stimulate cough or loosen tenacious secretions).

- Use clean rather than sterile technique during suctioning.

- Use clean (non-sterile) gloves when performing endotracheal suctioning. Gloves reduce the risk of introducing infectious material into the beneficiary's airway, the risk of infecting the caregiver, and the risk of transmitting organisms to others. Gloves may not be necessary when oropharyngeal suctioning is performed.

- Suction catheters handled appropriately as described may be reused. Catheters should be discarded after 24 hours. Tonsil tips may be cleaned, boiled, and reused indefinitely. If it is feasible to clean the suction device and subject it to high-level disinfection, it may be reused until its integrity is lost. Mechanical cleaning (i.e., removal of mucus and other organic material) should occur.

- Following the suctioning event, the beneficiary should be monitored for adverse reactions and the individual for whom pre-procedure hyperoxygenation and/or hyperinflation was indicated should be treated by the same method(s) after the procedure.

Infection Control

- Inform the beneficiary and any caregivers about the potential for transmission of both chronic and acute infection from the beneficiary to caregivers and from caregivers to the beneficiary and how to avoid that transmission including:

    - Careful hand washing and barrier protection when medically necessary.
    - Careful disposal of medical waste.
    - Adequate environmental air exchange.
    - Maximizing protection of beneficiary, family, and caregivers (e.g., influenza immunization) and minimizing exposure to persons with acute infections (e.g., limiting visitors with upper respiratory infections).
    - Ventilator circuits need not be changed more often than once each week. Maintaining a broken circuit as much as possible will lessen the likelihood of contamination.

Follow-up

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Periodically monitor ventilator settings and proper operation of equipment:

    - With each initiation of invasive mechanical ventilation, including altering the source of ventilation, as from one ventilator or resuscitation bag to another ventilator;
    - With each ventilator setting change; and
    - Visits as specified in the Service Plan.

Appendix D: Noninvasive Continuous Positive Airway Pressure (CPAP) and Bi-level Positive Airway Pressure (BiPAP)

This standard refers to beneficiaries on Continuous Positive Airway Pressure (CPAP) or Bi-level Positive Airway Pressure (BiPAP) for apnea or other disorders.

CPAP/BiPAP is an equipment-intensive procedure requiring an external positive pressure gas source or compressor and considerable training of personnel for proper setup and maintenance. CPAP is a continuous positive end-expiratory pressure applied to a beneficiary who is spontaneously breathing. BiPAP provides an inspiratory and expiratory pressure via a patient interface.

The supplier shall provide qualified personnel to perform the delivery, set-up, beneficiary education, monitoring (home visit or telephone call based on the clinical condition of the beneficiary) and follow-up services.

Inspection and Preparation

Intake

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Obtain a written prescription from the beneficiary's treating physician (based on a face-to-face examination to determine medical need) who has prescribed the noninvasive positive airway pressure ventilation equipment and related medical supplies before furnishing the equipment to the beneficiary; and
- Ensure the treating physician prescribes the exact specifications and details of all components of the equipment.

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Provide pertinent information to the treating physician to enable decisions regarding changes in CPAP/BiPAP systems.
- Document CPAP/BiPAP changes in the service plan record.
- Provide initial and monthly reports to the treating physician.
- Contact beneficiary and/or caregiver every two weeks for follow-up and quarterly onsite visits.

Equipment Management

See General Product-Specific Service Requirements

Delivery/Setup

In addition to General Product-Specific Service Requirements, the supplier shall:

- Ensure that any supplies associated with CPAP/BiPAP shall not be provided through a mail order service or through a distributor.
- Document CPAP/BiPAP changes in service plan records.
- Disinfect any reusable equipment (according to manufacturer's instructions) in between use by a different beneficiary.

Condition of the Home

(Refer to the General Product-Specific Service Requirements)

Condition of the Equipment

In addition to the General Product-Specific Service Requirements, the supplier shall provide and verify appropriateness of all CPAP/BiPAP equipment and supplies provided, including:

- CPAP/BiPAP Unit;
- Power Supply;
- Beneficiary interface:
  - Nasal mask that fits over the nose;
  - Nasal pillows which are inserted into the nostrils;
  - Mouthpiece;
  - Face mask; and
  - Tracheotomy.
- Tubing: for example, 6 feet of corrugated (flexible) tubing;
- Head gear and head strap;
- Filters;
- Humidifier (if medically indicated);
- Manometer for initial adjustments of resistor size and/or gas flow. Pressure manometers to ensure the correct prescribed pressure is maintained with all machines;
- Tissues and emesis basin or container for collecting or disposing of expectorated sputum; and
- Gloves, goggles, gown, and mask, as needed.

CPAP/BiPAP Unit

- Preset the pressure on the machine according to the treating physician's orders.
- Verify the unit has:
    - A power switch to turn the unit on and off;
    - An air outlet to which the tubing is connected; and
    - An air inlet where air is pulled into the unit through a filter(s), which removes dust and lint from incoming air.

Power Supply

- Advise the beneficiary and caregiver about appropriate electrical safety considerations, including proper grounding of outlets and connectors.
- Follow safety guidelines based on the number of prongs on the AC power connector.
- Refer to manufacturer's safety guidelines.
- Do not use an extension cord with the unit, unless unavoidable. If necessary, use an appropriate gauge to minimize risks.
- Do not plug the unit into an outlet that has other major appliances plugged into it.

Patient Interface/Circuit

The supplier shall check the interface/circuit for proper use and fitting:

- A facemask is used with CPAP and BiPAP systems.
    - The mask is determined by the:
        - Fit: adjust if the mask is too close to the beneficiary's face and/or the straps are too tight or loose;
        - Size: determine if the beneficiary needs small, medium, or large size; and
        - Style: determine by how it sits and feels on the beneficiary's face.
    - Full-face masks are indicated if the nasal mask is not used appropriately or if the patient breathes through the mouth.
    - Total facemasks are used by patients who are awake and alert and can guard their airways.
    - Ensure facemask covers the entire face and is made of clear plastic, lightweight faceplate.
- Nasal pillow equipment includes:
    - Colored or clear nasal pillows which fit snugly in the nostrils;
    - Tubing: which attaches to the air outlet on the CPAP/bi-level unit;

- Shell to which the nasal pillows are attached;
- Cushion;
- Adapters; and
- Headgear, which secures the nasal pillows to the nose and maintains a proper seal in both nostrils.

- Nasal mask equipment includes:

  - Tubing, which attaches to the air outlet on the CPAP/BiPAP;
  - Nasal mask, which fits snugly over the nose; and
  - Nasal mask headgear or nasal mask cap, which secures the nasal mask to the face.

Exhalation Ports

- Both nasal shells and nasal masks shall provide an opening to allow exhaled air to escape.

- Make sure not to block the exhalation ports or vents.

Humidifier

- Used when medically necessary, indicated by the treating physician.

- Used when a beneficiary needs substantial moisture during treatment.

- Refer to Invasive Mechanical Ventilation Therapy Standards, Appendix C for details.

Training/Instruction to Beneficiary and Caregiver

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

CPAP/BiPAP Unit

- How to turn the unit on and off.

- How to check for leaks in the system.

- How to set the pressure.

- Inform the beneficiary not to adjust the unit and to consult with their treating physician regarding questions about the prescribed setting.

- Proper positioning of the unit:

  - Place machine on a hard surface, next to or near where it is to be used or on a flat surface, such as a sturdy end table;

- Do not place the unit near a heat source or on carpet that could obstruct the flow of air around or underneath the unit;
- Do not place the unit above the patient's head so as to lessen the risk of pulling the tubing out while sleeping;
- Set up the unit to ensure adequate air circulation around the unit to ensure that the air inlet is not blocked by furniture, clothing or drapes; and
- If using a room humidifier, place at least six feet away from CPAP/BiPAP unit.

- CPAP/BiPAP unit should not be immersed in water or plugged in if wet.

- What to do if nasal CPAP/BiPAP unit fails, and the need to contact manufacturer or DME supplier for service if attempts to correct the situation are unsuccessful. The beneficiary and/or caregiver should never try to repair CPAP/BiPAP unit.

- CPAP/BiPAP should be used every night, the whole night for maximum benefit.

Tubing

- How to connect the tubing to the air outlet on the CPAP or bi-level unit:
  - Insert flex tubing into CPAP/BiPAP unit;
  - Connect the tubing to the nasal mask (if using a nasal pillow circuit, the tubing is already attached); and
  - Adjust the tubing so that it will not pull on the mask or nasal pillow circuit when the patient is lying down.
- If necessary, how to route the tubing up and over any bed headboard to reduce the tension on the mask or nasal pillow.

Interface

- Unit should be turned off until the nasal mask, nasal pillows, or facial mask and headgear are secured.

- How to attach mask/pillow/seals.

- How to assemble and fit the nasal mask, nasal pillow, or facial mask, which is based on product-specific instructions.

- How to unhook headgear straps:
  - Thread them through slots in the mask;
  - Fasten the mask onto the headgear straps; and
  - Adjust for the largest size possible.
- How to remove the mask.

- How to enhance mask comfort:

    - Wash face thoroughly before each use to remove excess oils (this will help to achieve a leak-free fit and prolong the useful life of the mask); and
    - Do not over-tighten the head strap. Over-tightening can irritate the face and cause damage to the mask.
- How to position and size the headgear, ensuring that a tight seal around the nose is achieved.

Nasal Mask

- How to properly arrange the headgear, so that, for example, the shorter straps are on the bottom.
- How to place the mask and headgear.
- How to arrange any additional equipment; for example, a spacer, comfort flap, or support ring.
- How to facilitate future adjustments by using a marker to mark the straps at the final strap position.

Nasal Pillow

- How to insert the pillows into the shell, making certain that pillows are inserted properly and are not leaking.
- How to remove headgear without unfastening it.
- How to attach the nasal pillow circuit assembly to the headgear.
- How to replace the headgear on the head.
- How to position the nasal pillows for a comfortable fit.
- How to attach the shell strap across the shell, and adjust the tension of the strap to attain a proper seal in both nostrils.

Connect Circuit to the CPAP or BiPAP Unit

- How to turn the equipment ON.
- Unit should automatically deliver prescribed pressure level.
- Turn on the CPAP/BiPAP machine to its full pressure before the mask is applied. For optimum fit, position straps on the headgear while the beneficiary is lying down and do not over tighten them. A small leak at the sides and/or the bottom of the mask is acceptable, but air leaking at the top of the mask can cause sore or dry eyes.

- Adequate removal of the beneficiary's exhaled gas shall occur either directly by the mask itself or by a separate whisper swivel device.

- Adjustment to CPAP/BiPAP may take up to four weeks.

- How to breathe properly while using the equipment.

- When and how to contact the supplier, physician or respiratory therapist with any problems or questions.

- Not to block exhalation port on the mask.

- If air leaks from mask or nasal pillows, readjust the mask or nasal pillows and the headgear.

- If the unit provides a leak test switch, turning switch to the leak test position will immediately achieve prescribed level of pressure. This allows check for leaks that might occur later when the unit ramps up to prescribed pressure level.

- How to adjust the nasal mask and headgear if any leaks are occurring.

- What to do if there is a need to get up during the night, including switching off the power, disconnecting the tubing from the nasal mask or nasal pillow assembly, leaving the mask or nasal pillows and headgear on head, reattaching tubing upon return to bed, and restarting equipment, as well as other possible procedures.

- To remove the headgear and mask or nasal pillows, it may be easiest to unhook or loosen only one of the bottom straps to remove the headgear in a quick one-step fashion.

- Daily cleaning of mask or pillows is recommended.

Humidifier

- If nasal drying occurs, use of a humidifier may be prescribed.

- The short flexible tubing connects the CPAP/BiPAP compressor to the humidifier.

- The long flexible tubing connects the humidifier to the mask.

- How to fill the humidifier appropriately with distilled water or boiled water after it has cooled to room temperature.

- Water should not come into contact with the equipment.

- Need to keep the humidifier turned off until ready to use.

- How to clean the humidifier based on manufacturer's instructions.

Filters

- How to change the filters.
- How to use the filters based on the manufacturer's instructions.
- Never place a damp filter in a CPAP/BiPAP unit.

Ramp

- If the treating physician has approved the use of a ramp, and if unit offers the ramp feature, then activate the ramp dial or the delay button as per the manufacturers' instructions.

Oxygen

- How to attach oxygen if prescribed.
- Always turn off the Oxygen unit before turning off CPAP/BiPAP, and turn on the Oxygen unit after turning on CPAP/BiPAP.
- Refer to Oxygen Standards, Appendix B, for additional specifications.

Safety Review

- Need to ground all electrical equipment.
- Never turn the unit on or off while oxygen is flowing through the circuit.
- How to follow cleaning procedures.
- How to contact DME supplier for routine and after-hours equipment problems.
- How to obtain help if a medical emergency arises.
- Need to notify the supplier immediately if the treating physician prescribes a change in the CPAP/BiPAP unit settings.
- When to contact the treating physician, including for symptoms of :
    - Runny nose, nasal, sinus or ear pain;
    - Recurrence or persistence of obstructive sleep apnea symptoms; and/or
    - Lightheadedness or dizziness.

Infection Control

- Need to observe Standard (Universal) Precautions and other specific infection control guidelines as appropriate.

- How to avoid the potential for transmitting both chronic and acute infection from patient to caregiver and from caregiver to patient, including by:
    - Careful hand washing and barrier protection when appropriate;
    - Careful disposal of medical waste;
    - Adequate environmental air exchange;
    - Maximizing protection of beneficiary, household members, and caregivers (e.g., influenza immunization) and minimizing exposure to persons with acute infections (e.g., limiting visitors with upper respiratory infections); and
    - Ventilator circuits need not be changed more often than weekly. Reducing the frequency of breaking the circuit lessens contamination risk.

Cleaning

- How to keep CPAP and BiPAP machines clean/disinfected per manufacturer's guidelines including unit, intake filter, headgear, tubing, swivel connector, and mask.

If Nasal CPAP/BiPAP Machine fails, check the following:

- Nasal CPAP/BiPAP unit is plugged in.
- On/off switch is ON.
- Wall outlet into which the nasal CPAP/BiPAP is plugged has power.
- Inlet air filter is clean and unblocked. Wash or replace as needed.
- Cooling fan is unblocked and a free flow of air is available.
- All tubing is securely connected.

Follow-up

In addition to General Product-Specific Service Requirements, the supplier shall:

- Coordinate the monitoring of the CPAP/BiPAP settings and the proper function of the equipment with the treating physician and beneficiary and/or caregiver:
    - With each initiation of CPAP/BiPAP;
    - With each CPAP/BiPAP setting change; and
    - On a regular basis as specified by the Service Plan.
- Ensure proper equipment function including, but not limited to:
    - Appropriate configuration of CPAP/BiPAP;
    - Alarm function;
    - Cleanliness; and

- Overall condition of all equipment.

- Provide access to frequent replacement items including filters, masks or headgear, and tubing.

Appendix E: Intermittent Positive Pressure Breathing (IPPB)

This standard refers to beneficiaries using Intermittent Positive Pressure Breathing (IPPB) in the home setting. IPPB is a technique to provide short-term or intermittent mechanical ventilation for the purpose of augmenting lung expansion, delivering aerosol medication, or assisting ventilation. IPPB can include pressure- and time-limited, as well as pressure, time, and flow-cycled ventilation and may be delivered to artificial airways and non-intubated patients.

The supplier shall provide qualified personnel for the delivery, set-up, beneficiary education, monitoring (home visit or telephone call based on the clinical condition of the beneficiary) and follow-up services.

Preparation and Inspection

Intake

See General Product-Specific Service Requirements

Service Plan

In addition to General Product-Specific Service Requirements, the supplier shall:

- Provide pertinent information to the treating physician to enable decisions regarding changes in IPPB therapy.
- Document all changes in ventilator settings and maintenance in the service plan record.
- Visit daily for first 72 hours, weekly until stable, then monthly.
- Initial and monthly report to treating physician.

Equipment Management

See General Product-Specific Service Requirements

IPPB Devices

- IPPB devices can be pneumatically driven or electrically powered. They are usually categorized as beneficiary-triggered, pressure- or flow-cycled mechanical ventilators.
- Most IPPB devices require a pounds/square inch (PSI) gas pressure source (e.g., compressed gas cylinder, bulk gas system, external or internal air compressor).
- Single-use IPPB devices are available to provide short-term or intermittent mechanical ventilation, augmenting hyperinflation and delivering aerosols.

- Single-use IPPB devices are not equipped with a redundant pop-off valve and thus should not be used with an endotracheal tube, and used cautiously with a mask.

- Tidal volume may be determined by using the tidal volume chart included with single-use IPPB instructions.

- For single-use IPPB equipment at home, the rental/purchase of a 50-PSI gas source is usually necessary.

- Single-use IPPB may be a safe and effective method of delivering IPPB without the need for conventional IPPB capital equipment.

Limitations of IPPB Devices

- All of the mechanical effects of IPPB are short-lived, lasting an hour after treatment.

- MDI or compressor-driven nebulizers may be considered the devices of choice for aerosol therapy to COPD and stable asthma patients.

- Only a very small percentage of the aerosolized medication optimally deposits in the airway. Delivery of a therapeutic medication dose via IPPB may require as much as a tenfold increase in medication amount when compared to MDIs.

- The device's effectiveness for ventilation and aerosol delivery depends on the design (e.g., flow, volume, and pressure capability as well as aerosol output and particle size) and on technique (e.g., coordination, breathing pattern, selection of appropriate inspiratory flow, peak pressure, and inspiratory hold).

- IPPB is an equipment-and labor-intensive method for delivering aerosol.

- Limited portability, lack of instruction, and/or lack of 50-psi gas source may affect beneficiary compliance.

Delivery/Setup

In addition to General Product-Specific Service Requirements, the supplier shall:

- Ensure that any supplies associated with IPPB shall not be provided through a mail order service or through a distributor.

- Document IPPB changes in the service plan; and

- Assess and reassess parameters as outlined per unit and/or treating physician orders.

Condition of the Home

See General Product-Specific Service Requirements

Condition of the Equipment

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Coordinate service with the respiratory goals and objectives based on the treating physician's prescription;
- Record relevant information on the ventilator sheet for insertion in the beneficiary's service plan; and
- Provide and verify appropriateness of all IPPB equipment and supplies provided, including:

Equipment and supplies

- IPPB Ventilator
- Large bore and connective tubing, "Universal" disposable circuits now used
- Nebulizer
- Adapters
- Patient connection (mouthpiece, lip seal, mask, 15-mm ETT connector), and if needed, nose clips
- Mouth seal and nose clips for beneficiaries who cannot use mouthpiece
- Mask (if mouth seal is not available)
- Tracheotomy adapter
- Manual or automatic valves
- Manometer may be connected between the modulator outlet and the nebulizer
- Internal or external power source
- Humidifiers
- Tissues, emesis basin, or sputum cup for collecting or disposing of expectorated sputum
- Gloves, gown, goggles, and/or mask with face shield as indicated
- Volume measuring device (handheld spirometer or other volume-collecting bag)
- Oral and/or endotracheal suction equipment
- Compressed air source

- Compressed gas source (air or oxygen)

Intermittent positive pressure breathing (IPPB) devices use pressure to passively fill the lungs when a breath is initiated. An incorporated manometer and mechanical valves serve to terminate the flow of inspired air when a predetermined pressure is reached on inhalation. IPPB breathing circuits are designed to nebulize inhaled medication. Most IPPB devices are powered by compressed air and are not suitable for home use.

IPPB Ventilator

The IPPB apparatus includes a precision flow-sensitive valve, which opens to a low preset level of inspiratory negative pressure (in beneficiaries with spontaneous respiration). This is immediately followed by a gradual increase of airway pressure to a preset level. At the onset of expiration, the valve closes and the airway pressure drops to the ambient atmospheric level, permitting expiration without external resistance. The expired air is released through a second valve, providing a minimal dead space. Compressed or room air is generally used to deliver aerosolized medications, however, mixtures of helium and oxygen have also been used in IPPB.

Circuits

- Precision molded baffles
- "Spill Proof" retain ring
- Siphon tube
- Capillary Tube

Oxygen

- When supplementary oxygen is necessary with nasal intermittent positive pressure ventilation, the optimal route for adding it to the ventilator circuit is unknown.
- Refer to Oxygen Standards, Appendix B, for additional specifications.

Tracheotomy

- Care shall be taken if administering IPPB to a beneficiary with a tracheotomy.
- Supervision of the beneficiary during treatment is recommended.
- Refer to Invasive Mechanical Ventilation Therapy Standards, Appendix C, for additional specifications.

Humidifiers

- If medically indicated, refer to Invasive Mechanical Ventilation Therapy Standards, Appendix C, for specifications.

Training/Instruction to Beneficiary and Caregiver(s)

In addition to General Product-Specific Service Requirements, the supplier shall:

- Instruct beneficiary on procedures, indications, and contraindications, and hazards of IPPB equipment and aerosol device;
- Fit mask and/or identify best application device for a beneficiary; and
- Instruct beneficiary on Universal Precautions and infection control and safety standards related to IPPB circuitry.

Self-administration of treatment

- Proper technique for administering treatment, measuring, and mixing medications.
- Proper use and cleaning of equipment.
- Optimal breathing patterns and coughing techniques.
- How to modify technique in response to adverse reactions and modify treatment duration or frequency depending on severity of symptoms.
- How to use a mouthpiece or--for individuals who cannot use mouthpiece--mouth seal and nose clips, or mask.
- How to place prescribed medication in the medication chamber, including proper positioning.
- What to do if dizziness occurs while taking treatment.

IPPB Machine

- How to turn on and operate the IPPB machine.
- How to place prescribed medication in the medication chamber, including proper positioning.
- How to allow the IPPB machine to fill the lungs and ensure that air is not escaping from the nose.
- How to clean and disinfect the IPPB machine per manufacturer’s guidelines.
- What to do if the IPPB machine fails, including failure to turn on or off.

Tubing

- How to attach the tubing to appropriate connections on the respirator, and tighten all connections. The connections and tubing may be sized so only the correct tubing will fit.

- How to attach tubing to the nebulizer and exhalation valve, as indicated.

Nebulizer

- How to connect all tubing and adapters.

- How to attach the IPPB device to the appropriate 50-psiG outlet, prepare medications, assemble the IPPB, attach nebulizer cap securely, and firmly connect the modulator to the nebulizer.

- How to ensure that all medication is nebulized.

- How to clean the IPPB by disconnecting the modulator from the nebulizer, removing the nebulizer cap, rinsing, and allowing it to air dry.

Infection Control

- Need to change nebulizers/IPPB circuits when visibly soiled, or according to the supplier's infection control policy.

- When to use personal protective devices to reduce exposure if a communicable disease such as active tuberculosis is present.

- When to use goggles, gloves, masks, and gowns as splatter shields and to reduce exposure to body substances if a communicable disease is present.

- How to sterilize, change, or clean nebulizers according to the supplier's or manufacturer's guidelines.

- Need to use only unit dose medication solutions, to reduce risk of cross contamination.

- Need to handle solutions from multi-dose sources aseptically and discard after 24 hours.

Follow-up

In addition to General Product-Specific Service Requirements, the supplier shall:

- Coordinate monitoring of settings and proper function of equipment:
    - With each initiation of IPPB therapy to the beneficiary;
    - With each setting change; and
    - On a regular basis as specified by individualized Service Plan.

- Note frequency of assessment of the IPPB system as part of service plan, based on response to therapy, and in conjunction with health care team, beneficiary, and caregivers.

Appendix F: Power Wheelchairs

This standard refers to beneficiaries using power wheelchairs including those with recline, tilt, and scooters (POVs). Medicare-approved accessories are also included.

The supplier shall provide the delivery/set-up, beneficiary education/training, and follow-up services.

Inspection and Preparation

Intake

In addition to General Product-Specific Service Requirements, the supplier shall:

- Obtain from the treating physician a prescription for the exact specifications and components of the wheelchair.

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Assess whether the size and known durability of the wheelchair appear to be appropriate relative to the beneficiary's approximate weight and height;
- Confirm that the wheelchair meets the beneficiary's medical disability and limitations; and
- Assess the beneficiary's planned use for the wheelchair relative to durability and style of wheelchair.

Equipment Management

In addition to General Product-Specific Service Requirements, the supplier shall:

- Provide the wheelchair according to the treating physician's order(s) and appropriate to the medical needs of the beneficiary, the care delivered, and the home.

Power Wheelchair

Upholstery

- Check back and seat for cracks and wear and repair or replace if any significant visible defects affecting comfort or safety.

Drive Wheel Assembly

- Pneumatic tires: check tread and pressure, adequacy of tread, repair, or replace tube if tire is not holding pressure.

- Solid tires: check for wear and tightness, adequacy of tread; repair or replace tire if tread is worn or tire is loose on wheel and cannot otherwise be tightened properly.

- Bearings: check condition of bearings; replace if bearings are worn and wheel is not spinning properly and cannot otherwise be corrected satisfactorily.

Caster Assembly

- Casters: check for caster wear and repair or replace if worn enough to affect safety or comfort.

- Bearings: check condition of caster bearings and stem bearings; repair or replace if bearings are worn and caster is not moving properly to the point of impairing mobility or affecting safety or comfort.

Front Rigging

- Hangers: check swing away/lift off mechanism and adjust, repair, or replace if hanger does not lock in place properly.

- Footplates: check footplate movement and adjust as needed.

- Leg rests: check elevating mechanism and adjust, repair, or replace if elevating leg rest does not maintain position. Check calf pads for wear and repair or replace if damaged or worn excessively.

Arm rest System

- Removable/Swing-away/Flip Back Armrests: check ease of use and locking/unlocking mechanism.

- Adjust armrest height.

- Inspect arm pads for wear: repair or replace if worn or torn enough to affect comfort.

Frame

- Frame parts: check side frames/crossbars/side post and ensure chair folds and unfolds smoothly or disassembles for transportation; repair, adjust, or replace as needed.

- Hardware: check all nuts, bolts, and attachment hardware for proper tightness.

    - Verify that no protruding hardware or equipment can injure the user's limbs.
    - Check all grips and tips for wear, and that they are tight and secure.

Motors

- Check mechanism for engaging/disengaging motors for wear and adjust as necessary.

Batteries

- Ensure battery is in good condition, terminals are free of corrosion, and connections are secure.

Accessories

- Check all accessory boxes for secure mounting.
- Verify that all accessories required are correctly installed and operational; repair, adjust, or replace as needed.

Charger

- Ensure charger and required accessories are present.

Drive Control

- Check hand control/module/battery box for secure mounting.
- Ensure chair operates properly in all directions/modes.

Drive Control Options

- Ensure secure mounting of all alternative drive control equipment
- Ensure chair operates properly in all directions/modes using alternative controls including, but not limited to head array system, sip n' puff system, single switch system, and single switch scanner system.

Kill Switch

- Ensure kill switch is present and operating if required.

Power Seating System Options

- Recline system: check that recline system works with switches/hand control.
- Tilt system: check that tilt system works with switches/hand control.
- Seat lift system: check that seat lift system works properly.
- Elevating leg rest system: check that elevating leg rest system works with switches/hand control.

Cleanliness

- Ensure chair and all accessories are thoroughly clean.

Delivery/Setup

Condition of the Home

In addition to General Product-Specific Service Requirements, the supplier shall:

- Assess the beneficiary's home setting and evaluate for safety concerns, e.g. stairs, width of doorways, doorway thresholds, placement of furniture, carpet pile, etc.

Condition of the Equipment

See General Product-Specific Service Requirements

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

Leg rests/foot rests

- How to release the leg rests/foot rests from the forward position, move them to a swing-away or lift off position, and remove them from the chair.
- How to lock leg rests/foot rests in the forward position.
- How to check for secure installation.
- How to move footplates from resting to vertical position and back.
- How to protect limbs from being struck by leg rests or foot rest/plates during removal and installation and/or vertical positioning.

Adjust leg rests/foot rests

- How to adjust leg rest/foot rest length, indicating where to find the adjustment bolt. Adjust for optimal position with beneficiary.
- For elevating leg rests: how to elevate and lower the leg rests.
- Check that no bolts or sharp items are protruding.
- Adjust angle of footplate.

Remove and install arm rests

- How to release and remove armrest from chair, as well as how to install and secure.

- For chairs with desk-length detachable arms: how to move the arm rests forward by swapping and reversing the arms.

- How to protect the limbs during these procedures.

Adjust height of arm rests

- How to adjust armrest height, where to find the securing lever, and how to snap armrest into place. Adjust for optimal position with beneficiary.

- How to test security of the settings.

Lock and unlock the wheel locks

- Location of locks and how to activate and disengage them, as well as how and when to adjust them.

Position anti-tip tubes/devices

- How to adjust the height of, remove, and reinstall anti-tip tubes/devices.

- Verify the appropriateness of the position of the anti-tip tubes/devices with respect to beneficiary's height and weight, medical conditions, and expected operating conditions.

Inflate pneumatic tires

- How to check tires for proper pressure and how to inflate them. Adjust pressure if necessary.

- What to do in case of a flat tire at home or in the community.

Adjust pelvic/lap belt

- How to adjust, lock, and unlock belt.

- If a pelvic positioning belt is used: how to adjust, secure, and check for proper positioning.

Prepare wheelchair for transportation

- How to remove and reposition components for transportation and how to secure in each position.

- How to fold/unfold or prepare wheelchair frame for transportation.

Backposts

- How to adjust height of backposts/back upholstery.

- How to adjust angle of backpost.

Remove and install seat support cushion

- How to remove and reposition seat support cushion on wheelchair.
- How to adjust for posture and comfort of beneficiary.

Remove and install back support cushion

- How to remove and reposition back support cushion on wheelchair.
- How to adjust for posture and comfort of beneficiary.

For all methods of driving power wheelchair including alternative drive systems

- How to program wheelchair electronics for safe wheelchair operation.
- How to turn chair on/off and control speeds.
- How to drive power wheelchair safely.
- How to use any emergency features associated with drive control system.

If recliner power wheelchair

- How to recline and incline back system.
- How to use any emergency features associated with system.

If tilt-in-space power wheelchair

- How to tilt seating system forward and rearward.
- How to use any emergency features associated with system.

If power elevating leg rests

- How to elevate and lower leg rests.
- How to use any emergency features associated with system.

Use of other special features

- How to use all power wheelchair features including but not limited to scooter (POV) swivel seat, scooter (POV) tiller, vent tray system, and transportation tie down system.
- How to use any emergency features associated with these features.

Ability to manually operate wheelchair

- How to engage/disengage brake release levers or motors for free wheel pushing.

Charge battery

- How to determine if battery needs to be charged.
- How to charge the wheelchair battery.
- How to troubleshoot charging problems.
- How to determine when the battery needs to be replaced.

Safety Review

- Safe use of wheelchair.
- How to go up and down curbs.
- How to maneuver in tight corridors.
- How to navigate wheelchair in hazardous conditions (i.e., uneven, wet, or slippery surfaces).
- How to use pelvic positioning belt and safety belt.
- Hazards of driving wheelchair under the influence of alcohol or other substances
- Hazards of driving wheelchair while using a cell phone

General

- How to clean and maintain the wheelchair.
- When and who to contact if wheelchair no longer meets the beneficiary's medical needs or requires modification.
- How to contact supplier with questions and need for adjustments and repairs.

Follow-up

See General Product-Specific Service Requirements

Appendix G: Manual Wheelchairs

This standard refers to beneficiaries using manual wheelchairs in the home setting, including those with recliner and tilt-in-space features, standard wheelchairs, heavy-duty wheelchairs, lightweight and ultra lightweight wheelchairs chairs, and hemi wheelchairs. Armrests, leg rests/footplates, anti-tipping devices, and other Medicare-approved accessories are also included.

The supplier shall provide the delivery/set-up, beneficiary education/training, and follow-up services.

Inspection and Preparation

Intake

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Obtain from the treating physician a prescription for the exact specification and components of the wheelchair.

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Document whether the size and known durability of the wheelchair appear to be appropriate relative to the beneficiary's approximate weight and height;
- Confirm that the wheelchair is appropriate for the beneficiary's disability and limitations; and
- Assess other aspects of wheelchair, including beneficiary's planned use (need to navigate through narrow doorways, etc.) relative to durability and style of wheelchair.

Equipment Management

See General Product-Specific Service Requirements

Manual Wheelchair

Upholstery

- Back: check for cracks, wear, and repair or replace any defects that could affect beneficiary comfort or safety.
- Seat: check for cracks, wear, and repair or replace any defects that could affect beneficiary comfort or safety.

Rear Wheel Assembly

- Tires:

- Pneumatic tires: check treads and pressure; replace tire if tread is worn, replace tube if tire is not holding pressure.
- Solid tires: check for wear and tightness; replace tire if tread is worn or tire is loose on wheel and cannot otherwise be tightened properly.
- Spoke rim: ensure proper spoke tightness and true rim.

- Bearings: check condition of bearings; replace if bearings are worn and wheel is not spinning properly and cannot otherwise be corrected satisfactorily.

- Wheel removal: check quick-release axles and ensure axles lock wheel in place.

- Hand rims: check for rim tightness and sharp or rough surfaces.

- Wheel locks/grade aides: check locking/unlocking mechanism and adjust; replace if unable to lock wheel adequately.

Front Caster Assembly

- Casters: check for wear and replace if worn.

- Bearings: check condition of caster bearing and stem bearings; replace if bearings are worn and caster is not moving properly and problem cannot otherwise be corrected satisfactorily.

Front Rigging

- Hangers: check swing away/lift-off mechanism and adjust; replace if hanger does not lock in place properly and problem cannot otherwise be corrected satisfactorily.

- Footplates: check footplate movement and adjust.

- Leg rests: check elevating mechanism and adjust; replace if elevating leg rest does not maintain position and problem cannot otherwise be corrected satisfactorily; check calf pad for wear and replace if torn or worn.

Arm rest system

- Removable/swing-away/flip back armrests: check ease of use and locking/unlocking mechanism.

- Adjust armrest height.

- Inspect arm pads for wear; replace if worn or torn.

Frame

- Frame parts: check side frames/crossbars/side post and ensure chair folds and unfolds smoothly; repair, adjust, or replace as needed.

- Hardware:
    - Check all nuts, bolts, and attachment hardware for proper tightness; repair, adjust, or replace as needed.
    - Verify that no protruding hardware or equipment can injure the limbs of the rider.
- Check all grips and tips for wear; should be tight and secure.

Accessories

- Verify that all required accessories (e.g., cane/crutch holder, oxygen holder, cushions) are correctly installed and operational; repair, adjust, or replace as needed.

Cleanliness

- Ensure chair and all accessories are thoroughly clean.

Recliner manual wheelchair

- Check recline mechanism and adjust to enable easy, complete operation throughout entire range of motion.

Tilt-in-space manual wheelchair

- Check tilt mechanism and adjust to enable easy, complete operation throughout entire range of motion.

Power assist wheels

- Wheel mechanism: check method to adjust power drive system.
- Batteries: check batteries and charger system.

Delivery/Setup

See General Product-Specific Service Requirements

Condition of the Home

In addition to General Product-Specific Service Requirements, the supplier shall:

- Assess the beneficiary's home setting and evaluate for safety concerns related to wheelchair use; for example, stairs, width of doorways, doorway thresholds, placement of furniture, carpet pile, etc.

Condition of the Equipment

See General Product-Specific Service Requirements

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

Remove and install leg rests/foot rests

- How to release the leg rests/foot rests from the forward position, move them to a swing-away or lift off position, and remove them from the chair.
- How to lock leg rests/foot rests in the forward position.
- How to check for secure installation.
- How to move footplates from resting to vertical position and back.
- How to protect limbs from being struck by leg rests or foot rest/plates during removal and installation and/or vertical positioning.
- For elevating leg rests, how to elevate and lower the leg rests.
- How to adjust leg rest/foot rest length, indicating where to find the adjustment bolt. Adjust for optimal position with beneficiary.
- How to check that there are no protruding bolts or sharp items that can cause injury.
- How to adjust angle of footplates.

Remove and install arm rests

- How to release and remove armrest from chair, as well as how to install and secure.
- For chairs with desk-length detachable arms, how to move the arm rests forward by swapping and reversing the arms.
- How to protect the limbs during these procedures.

Adjust height of arm rests

- How to adjust armrest height, where to find the securing lever, and how to snap armrest into place. Adjust for optimal position with beneficiary.
- How to test security of the settings.

Lock and unlock the wheel locks

- Location of locks and how to activate and disengage them, as well as how and when to adjust them.

Position anti-tip tubes/devices

- How to adjust the height of anti-tip tubes/devices, how to remove them, and how to reinstall them.

- How to verify the appropriateness of the position of the anti-tip tubes/devices with respect to beneficiary's height and weight, medical condition, and expected operating conditions.

Use tipping levers/anti-tip devices

- For chairs with tipping levers, how to safely tip the wheelchair.

Inflate pneumatic tires

- How to check tires for proper pressure and how to inflate them. Adjust pressure if necessary.

- What to do in case of a flat tire at home or in the community.

Adjust pelvic/lap belt

- How to adjust belt, lock and unlock.

- If a pelvic positioning belt is used, how to adjust, secure, and check for proper positioning.

Prepare wheelchair for transportation

- How to remove and reposition components for transportation.

- How to fold/unfold or prepare wheelchair for transportation and how to secure in each position.

- How to remove and install quick-release rear wheels ensuring axle is locked in place.

- How to install and remove wheel and lock the axle.

Rear wheel and caster position

- How to adjust rear wheel position for optimal propelling, seat height and seat angle of manual wheelchair.

- How to adjust caster position for optimal seat height, seat angle and wheelchair maneuverability.

Back posts

- How to adjust height of back posts/back upholstery.

- How to adjust angle of back post.

Remove and install seat support cushion

- How to remove and reposition seat support cushion on wheelchair.
- How to adjust for posture and comfort of beneficiary.

Remove and install back support cushion

- How to remove and reposition back support cushion on wheelchair.
- How to adjust for posture and comfort of beneficiary.

If recliner wheelchair

- How to recline and incline back system.

If tilt-in-space wheelchair

- How to tilt seating system forward and rearward.

Power assist wheels

- Demonstrate use of wheel system.
- Demonstrate method to change batteries.

Safety Review

- How to use wheelchair safely.
- How to go up and down curbs.
- How to maneuver in tight corridors.
- How to navigate wheelchair in hazardous conditions (i.e., uneven surfaces, wet/slippery, uphill, downhill, up and down incline).
- How to use the pelvic positioning belt versus the safety belt.
- How to handle emergencies (i.e., flat tires, techniques for righting an overturned chair, etc.)

General

- How to clean and maintain the wheelchair.
- When and who to contact if wheelchair no longer meets his/her needs or requires modification.

- How to contact the supplier with questions and need for adjustments and repairs.

Follow-up

See General Product-Specific Service Requirements

Appendix H: Diabetic Equipment and Supplies

This standard refers to beneficiaries using diabetic equipment and supplies in the home setting.

Inspection and Preparation

See General Product-Specific Service Requirements

Intake

See General Product-Specific Service Requirements

Service Plan

See General Product-Specific Service Requirements

Equipment Management

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Furnish a home blood glucose monitor that is appropriate for any physical limitations such as visual impairment.

Delivery/Setup

In addition to the General Product-Specific Service Requirements:

- When replacing supplies through mail order delivery, the supplier shall ensure the instructions on the operation, safety, maintenance, repair, replacement, warnings, and manufacturer's instructions are packaged with the products.

Condition of the Home

See General Product-Specific Service Requirements

Condition of the Equipment

See General Product-Specific Service Requirements

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

Equipment Specific Instructions

Lancet (Lancing Device and Platforms)

Equipment Usage

1. How to use lancet properly to obtain a blood sample.
2. How to dispose of lancet/platform safely.
3. How to clean and maintain lancet device and platform.

Safety

- How to dispose of lancets:
    - Do not discard them into a household trashcan, as a used lancet might accidentally stick someone; and
    - Place used lancets into a plastic container, such as an empty laundry detergent bottle or plastic water bottle. Seal the container when it is about three-quarters full.
- Check with local trash disposal agency about proper disposal of lancets.

Laser skin-piercing device and disposable film cartridge

Equipment Usage

- How to select proper depth of penetration, set and use the device, and obtain a blood sample for the glucometer.
- How to clean and maintain the device.
- Need to keep battery properly charged or to replace, as indicated.
- How and when to replace the disposable film/lens shield cartridge.

Home Blood Glucose Monitor

Equipment Usage

- Usage is likely to vary slightly for each model of home blood glucose meter.
- How to prepare for use, insert a lancet in the lancet device, use test strips, use lancet device to obtain a blood sample, use blood glucose monitor to get the results, and record test results if the monitor does not automatically record them.

Home Blood Glucose Monitor with integrated lancing/blood sample

- These monitors have an integrated lancing device and therefore, do not require a separate lancing device as with typical monitors.
- Some of these monitors also do not require test strip handling or coding.
- Need to follow manufacturer's manual for specific usage instructions.

Home Blood Glucose Monitor with integrated voice synthesizer

- These monitors use a voice prompt to guide visually impaired users through the testing process, step-by-step. See owner's manual for specific usage instructions.

All Glucometers

Cleaning/Maintenance

- How to keep glucose monitor clean.
- Need to avoid getting moisture in the code key slot or in the test strip opening.

Troubleshooting

- What to do if an unexpected result is obtained.
- How and when to check and replace battery.

Factors that can affect the accuracy of a test include:

- Any alcohol in the drop of blood from cleaning skin with rubbing alcohol. Let the area dry completely before sticking it with the lancet;
- Dirty hands. Wash hands thoroughly with soap and water before testing;
- Wet hands. Even a small amount of water can affect blood sugar results. Dry hands thoroughly after washing them;
- Scraping the skin or milking the blood drop and contaminating it with other materials such as fluids or skin;
- Using too small or too large a drop of blood;
- Blood glucose monitors cannot detect very low (below 40 mg/dL or 2.2 mmol/L) or very high (above 400 mg/dL or 22.2 mmol/L) blood sugar levels;
- Blood sugar levels vary according to diet, activity level, and insulin or diabetes medication;
- Improper coding of the monitor;
- A monitor that has been dropped or damaged;
- Test strips that have been stored improperly or have expired;
- Multiple vials of testing strips from different calibration codes are being used at the same time;
- Using test strips that are damaged or previously used;
- Not using the correct brand of test strips;

- Monitor has been stored at improper temperature (extreme hot or cold);
- Extremes of humidity (>90% or <10% relative humidity);
- Extremes of altitude (greater than 10,000 feet or 3000m ft above sea level); and
- Significant body fluid loss or dehydration.

Normal, low and high calibrator solution/chips

Equipment Usage

- How to use control solution/chips to maintain accurate readings from home blood glucose monitor.
- Need to check the test strip vial label for the correct calibrator solution/chip range before running a test. If the monitor is functioning properly, results will fall within this specified range.
- How to insert test strip with calibrator solution or calibrator chip into monitor to get results.
- When to run a calibrator solution/chip test: before first use of system, weekly thereafter; if test strip vial cap left open, blood glucose monitor dropped, test results are higher or lower than expected; and to check the performance of the blood glucose monitor and test strips.

Storage

- How and where to store.
- How long to store a batch of calibrator solution/chips after opening the vial.

Blood glucose test/reagent strips (for monitor)

These test strips are to be used with the home blood glucose monitor. The supplier shall educate beneficiary and/or caregiver on usage and storage of test strips.

Usage

- Need to use correct test strips. Each home blood glucose monitor requires a specific type of test strip, usually brand specific (check manual).
- Need to check expiration date on the bottle of testing strips. Do not use test strips after the expiration date on the bottle.
- Need to match code number on the testing strips bottle with the number on the meter.
- How to change code number on monitor, if indicated.

- How to handle and store test strips.

Follow-up

See General Product-Specific Service Requirements

Appendix I: Customized Orthotics and Prosthetics

This standard refers to beneficiaries using customized orthotics and prosthetics in the home setting.

Customized orthotics and prosthetics involves knowledge and understanding of human anatomy and beneficiary factors such as height, weight, level of physical activity, overall health, comorbidities and the specific diagnosis to make each fitting unique to that beneficiary. These standards address customized orthotics and prosthetics that *require the qualification and expertise of a certified or licensed orthotists, prosthetists, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC).* The supplier shall be trained in a broad range of treatment options to ensure that the item prescribed is optimal for the beneficiary's condition. For customized items, the provision of care requires access to a facility with the equipment necessary to fulfill the supplier's responsibility to provide follow-up treatment and fabrication/modification of the specific device.

Definitions of Terms

The following terms are used to describe the types of customized devices referred to in this standard:

Custom Fabricated: A device fabricated to comprehensive measurements and/or a mold or patient model in accordance with a prescription that requires substantial clinical and technical judgment in its design, fabrication, and fitting.

Custom Fitted High: A prefabricated device modified for use in accordance with a prescription that requires substantial clinical judgment (involving high patient assessment, formulation of a treatment plan and follow-up skills) and substantive alteration (involving medium technical implementation skills) for appropriate use.

Custom Fitted Low: A prefabricated device modified for use in accordance with a prescription that requires substantial clinical judgment (involving some patient assessment, formulation of a treatment plan and follow-up skills) and substantive alteration (involving low technical implementation skills) for appropriate use.

Suppliers shall have established written beneficiary management policies and procedures that address, at a minimum, the evaluation, fitting and follow-up of customized orthotic and prosthetic beneficiary care. These policies and procedures shall be available at each physical location of the supplier and will require the following:

- A process for privileging non-credentialed or licensed professional staff and maintain evidence that the professional staff are complying with such policies; and

- All customized orthotic/prosthetic care shall be provided under the direction of a privileged and where appropriate, licensed, or credentialed practitioner who is available within 60 minutes of beneficiary notification or physically consult with the beneficiary.

Inspection and Preparation

Intake

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Assess the beneficiary and perform a comprehensive beneficiary history (e.g. demographic characteristics, family dynamics, previous use of an orthosis or prosthesis, diagnosis, work history, vocational activities, signs and symptoms, pertinent medical history (including allergies to materials), reimbursement status, beneficiary expectations, results of diagnostic evaluations);

- Consult with the treating physician before finalizing a treatment plan; and

- Consult technical component/material resources as required.

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Formulate a service plan by performing a diagnosis-specific functional clinical examination (e.g. manual muscle testing and evaluation of sensory function, cognitive ability, range of motion, joint stability, skin integrity, and compliance);

- Communicate to beneficiaries and/or treating physicians the recommended service plan and any optional plans, including disclosure of potential risks/benefits involved;

- Select appropriate orthosis/prostheses and specifications based on beneficiary criteria to ensure optimum strength, durability, and function as required;

- Assess devices for structural safety and ensure that manufacturer's guidelines are followed prior to beneficiary fitting/delivery (e.g., beneficiary weight limits: ensure strapping, laces, and velcro closures work appropriately and do not demonstrate defects);

- Refer beneficiaries back to the treating physician or other healthcare provider for intervention beyond the orthotist's and/or prosthetist's scope of practice;

- Solicit feedback from beneficiaries and treating physicians to determine status (e.g., wear schedule/tolerance, comfort, perceived benefits, perceived detriments, ability to don and doff, proper usage and function, overall beneficiary satisfaction);

- Assess beneficiary skin condition (e.g., integrity, color, and temperature); and

- Formulate treatment goals and expected orthotic or prosthetic outcomes (e.g. reduce pain/increase comfort, enhance function and independence, provide stability, prevent deformity, address cosmetic issues, and/or promote healing).

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

- How to use, maintain, and clean the orthosis/prostheses (e.g., wearing schedules, therapy, residual limb hygiene, other instructions).
- How to inspect for pressure points or edge pressures.
- How to don and doff the device, including how to adjust straps, hinges, Velcro, laces for proper fit and tightness.
- Need for daily skin inspections for excessive redness, irritation, skin breakdown, or swelling.
- Appropriate socks/shoes to accommodate orthotic device where appropriate.
- Confirm that beneficiary has a follow-up appointment scheduled, if necessary.
- Appropriate "wear schedule" and schedule for tolerance of device.

Follow-up

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Have access to a facility with the equipment necessary to provide follow-up treatment and fabrication/modification of the specific device;
- Inform beneficiary of recommended maintenance;
- Inform beneficiary to contact orthotist if changes in beneficiary skin condition (e.g., integrity, color, temperature, and volume) or general health, height, and weight, and note any changes;
- Set up return appointments for periodic evaluation based o the ongoing individualized care plan
- Monitor with a frequency based on the ongoing individualized service plan and the beneficiary's current medical condition;
- Document that the beneficiary, family, and/or treating physician have been informed of the procedure involved in receiving the orthosis or prosthesis, possible risks, and time involved in the process; and
- Complete delivery process after achieving optimal fit of orthoses/limb prostheses; and

- Provide appropriate patient follow-up care, consistent with the service(s) provided, the patient's diagnosis, orthotic/prosthetic care rendered, and recommendations.

Appendix J: Enteral Nutrition

This standard refers to beneficiaries using enteral nutrition therapy in the home setting. The complete enteral nutrition therapy requires the following equipment:

- Formula;
- Feeding Tubes;
- Administration Kits; and
- Feeding Pumps.

If the beneficiary is receiving home health services, the enteral nutrition clinical services are provided by the home health agency. If the beneficiary resides in a Skilled Nursing Facility (SNF), the enteral nutrition clinical services are provided by the SNF.

If the beneficiary does not receive home health services or does not reside in a SNF, the supplier shall provide qualified staff trained in enteral nutrition to implement beneficiary education, clinical monitoring, and follow-up.

Inspection and Preparation

See General Product-Specific Service Requirements

Intake

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Employ or contract with one or more appropriately trained persons who are knowledgeable and experienced in the clinical use of enteral nutrition therapy.
- Request a copy of the initial assessment by the clinician, which includes an evaluation of the patient's medical and nutritional condition, nutritional needs, and potential to tolerate the prescribed enteral nutrition regimen.

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Implement the treating physician's treatment plan specific to the beneficiary and consistent with the physician's treatment plan;
    - Only the treating physician can order changes in the enteral nutrition formulas.
    - Document any enteral nutrition therapy changes in the service plan.
- Follow up with the treating physician to confirm the prescribed enteral formulas therapy regimen and, if appropriate, to recommend possible changes or refinements

to the prescribed regimen (such as modifying the prescribed enteral nutritional formula, dilution, method of administration, etc.); and

- Document all enteral nutrition beneficiary contacts in the service plan.

Equipment Management

See General Product-Specific Service Requirements

Delivery/Set-Up

See General Product-Specific Service Requirements

Condition of the Home

See General Product-Specific Service Requirements

Condition of the Equipment

See General Product-Specific Service Requirements

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

- How to set up and prepare formulas, including hand washing and handling of formula, feeding tubes, bags and sets using clean technique;

- Patient feeding, including positioning of the beneficiary during and after the feeding and flushing water into the beneficiary's tubing with syringe before and after the feeding, if ordered by the treating physician;

- Storage of unused formulas, including covering with plastic and marking the date on opened containers and bags of formulas, storing opened cans and bags of formulas in a refrigerator, and using open formulas within 24 hours;

- Steps to resolve common feeding problems, including contacting the treating physician regarding common feeding problems such as constipation and nausea/vomiting;

- Assembly, use, storage and maintenance of all equipment and supplies, including the feeding pump, pole, feeding bags or sets, and formulas;

- Review of the information contained in the admission packet, including the supplier's phone number, the emergency phone number, written instructions on the nutrition therapy, hand washing, and cleaning the gastrostomy/jejunostomy site;

- Need to maintain a safe and clean environment for preparing and administering the enteral nutrition therapy, such as access to running water, electricity, a clean area for preparing the formulas and a mechanism for contacting the supplier and/or emergency medical assistance;

- Setting up the necessary equipment, including:

    - Setting up the pole and attaching the pump;
    - Connecting the pump to the electric outlet and explaining battery operated back-up features;
    - Features of the pump;
    - How to load the pump (with appropriate references to the written instructions).
    - How to respond to the pump's alarms; and
    - Safe and appropriate use of supplies and equipment, including handling malfunctions and problem solving.
- Cleaning the equipment.

Note: If the beneficiary does not require a pump, the supplier should review the gravity feeding system or syringe feeding system with the beneficiary and/or caregiver.

The supplier should provide or coordinate access to information about the following:

- General principles of enteral nutrition therapy, including indications for use, the specific treatment, formulas storage and handling;

- Aseptic/clean techniques;

- Recognition and appropriate response to various types of complications;

- Description of any necessary functional limitations or activity restrictions;

- Emergency numbers and procedures to contact appropriate individuals, as needed; and

- Home safety.

Feeding Tubes

Nasogastric Tubes

Proper Tube Placement

Questions regarding tube placement should be directed to the treating physician in the following cases and the beneficiary should be instructed not to administer formula or medication via the tube:

- After vomiting or retching;

- Immediately after severe coughing;
- If the tube is accidentally pulled;
- If the beneficiary is uncertain about proper tube placement;
- If there is a change in condition such as persistent or progressive abdominal pain, cramping, bloating, fullness or burning with feedings; and
- If there is unusual leakage around the tube.

Gastrostomy or Jejunostomy Tube

Proper Tube Placement

Questions regarding tube placement should be directed to the treating physician in the following cases and the beneficiary should be instructed not to administer formula or medication via the tube:

- Before each intermittent/bolus feeding and every 8 hours with continuous feedings;
- Before each medication administration;
- If the tube is accidentally pulled;
- If the beneficiary is uncertain about proper tube placement;
- If there is a change in condition such as persistent or progressive abdominal pain, cramping, bloating, fullness or burning with feedings; and
- If there is unusual leakage around the tube.

Troubleshooting

- Need to check the markings at the base of the tube before feeding/medications.
- Slight in-and-out movement of the tube is normal and can help prevent complications resulting from the bolster being too tight against the abdomen.
- Need to call the treating physician or healthcare provider if the number at the base of the tube changes by two or more.

Formulas

Storage and Safety

- Need to store unopened cans of enteral formula at room temperature to avoid temperature extremes (prevent product from freezing and store unopened below 86^{o}F).

- Need to remove opened formula cans and prepared powdered formulas from refrigeration no more than one hour prior to administration and discard 24 hours after opening or reconstitution. Follow manufacturer's guidelines. Administer enteral formula at room temperature.

- Need to cover opened cans of formula with plastic wrap or another cover.

- Need to check expiration dates on all containers and not use beyond expiration date.

- Before opening canned enteral formula, rinse the top of the can and the can opener with hot water and dry with a clean towel.

- Do not use ingredients from damaged containers.

- When mixing or pouring formula, do not touch the inside of the container or the formula with fingers.

Administration Kits

Syringe Feeding

- Rinse the syringe after use and store in a clean area.

- Discard syringe after 24 hours or according to manufacturer's guidelines.

Gravity Feeding

- Replace feeding bag/set per manufacturer's instructions.

Pump Feedings

- Replace feeding bag/set per manufacturer's instructions.

- Clean feeding pumps weekly, or as needed per manufacturer's instructions.

- Annually, clean the pump more thoroughly and calibrate per the manufacturer's instructions.

- Have feeding pumps inspected and maintained on a regular schedule by trained personnel.

The supplier should instruct the beneficiary and/or caregiver to consult with their treating physician if the following problems occur:

- Redness, swelling, leakage, sores, or pus around the tube;

- Blood around the tube, or in the stool;

- A change of more than two numbers at the bolster near the base of the tube;

- A clogged tube that cannot be cleared;
- If the feeding tube becomes dislodged, turn off the pump and call treating physician immediately.
- Nausea that lasts more than 24 hours;
- Recurrent vomiting of more than 8 hours;
- Diarrhea that continues for more than 24 hours;
- Gas or bloating that lasts for more than 24 hours or prevents receiving next tube feeding;
- Constipation that lasts for more than 3 days, depending on patient's normal frequency of bowel movements, or hard stool for more than 5 days;
- Weight loss of more than 2 pounds in one week; and/or
- Any unusual weakness or fever.

Follow-up

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Review the service plan periodically with the treating physician or clinician who is managing the beneficiary in the home, as necessary to address:
  - Changes in the beneficiary's clinical condition;
  - Changes to the treating physician's treatment plan; and
  - Identification of new or recurring concerns and/or needs.
- Monitor via monthly telephone calls to beneficiary.
- Make follow-up visits when indicated.

Appendix K: Electric and Manual Hospital Beds

This standard refers to beneficiaries using electric and manual hospital beds with and without side rails in the home setting.

Inspection and Preparation

See General Product-Specific Service Requirements

Intake

See General Product-Specific Service Requirements

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Document whether the size and known durability of the bed appears to be appropriate relative to the beneficiary's approximate weight and height.
- Confirm that the bed is appropriate for the beneficiary's medical disability and limitations.

Equipment Management

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Provide the hospital bed according to treating physician's order(s) and appropriate to the medical needs of the beneficiary, the care delivered, and the home.

Electric Hospital Bed

Mechanical Inspection

- Inspect all bed components for damage or excessive wear.
- Visually examine all welds for cracks.
- Inspect the head and foot spring sections for bending, warping, or damage.
- Check drive shaft and drive shaft connections for bending, damage, or excessive wear.
- Inspect pull tubes and mounting hardware for bending, damage, or excessive wear.
- Inspect all bolts and rivets to ensure that they are securely tightened and functioning properly.
- Check sleep surfaces to ensure all links are intact.

- Inspect bed ends for proper operation.
- Inspect cables and pulleys for wear.
- Inspect screws for lubrication.
- Check casters to ensure they lock, if applicable, and roll properly.

Electrical Inspection

- Inspect all electrical bed components for damage or excessive wear (i.e. cracked or broken housings, or worn components).
- Check pendant, power, and motor cords for chafing, cuts, or excessive wear.
- Ensure that all plugs are fully attached and free of damage.
- Ensure that the cable lock on junction box is properly positioned and locked.
- Check all functions including:
    - Head raises and lowers properly;
    - Foot raises and lowers properly; and
    - Bed ends raise and lower properly.
- Assess adequacy of electrical outlet and grounding.

Manual Hospital Bed

Mechanical Inspection

- Inspect all bed components for damage or excessive wear.
- Visually examine all welds for cracks.
- Inspect the head and foot spring sections for bending, warping, or damage.
- Inspect pull tubes and mounting hardware for bending, damage, or excessive wear.
- Inspect all bolts and rivets to ensure that they are securely tightened and functioning properly.
- Check sleep surfaces to ensure all links are intact.
- Inspect bed ends for proper operation.
- Inspect cables and pulleys for wear.
- Inspect screws for lubrication.

- Check casters to ensure they lock, if applicable, and roll properly.

Delivery/Setup

Condition of the Home

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Assess the beneficiary's home setting relative to the bed and evaluate for safety concerns, e.g. power needs for electric hospital bed and support surface; and
- Check that floors appear to be able to support the weight of the bed.

Condition of the Equipment

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Document whether the size and known durability of the bed appear to be appropriate relative to the beneficiary's approximate weight and height;
- Note the beneficiary's disability relative to the type of hospital bed;
- Deliver the bed and confirm that it is operational;
- Verify that the order includes the correct equipment; and
- Ensure that bed and any accessories are present and in working order.
- Ensure that bed is clean.

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

- Bed up/down feature;
- Bed head up/head down feature;
- Bed legs up/legs down feature;
- Floor brake use;
- Side rail use; and
- For electric hospital bed: manual operation of all features in case of power failure or other emergency.

Safety Review

- How to use the bed system safely.
- How to avoid entrapment in the bed or between bed and side rails, etc.
- What to do in case of bed malfunction, failure of powered components, or power outages.

Follow-up

See General Product-Specific Service Requirements

Appendix L: Support Surfaces

This standard refers to beneficiaries using support surfaces in the home setting. Support surfaces may be part of a bed system or a wheelchair system.

Support surfaces for the bed are divided into 3 categories.

- Category 1 includes mattress overlays and mattresses. Overlays include air pressure pads, water pressure pads, dry pressure pads, and gel/gel like pressure pads. Most of the overlays are non-powered but some are powered and require a pump.

- Category 2 includes special mattresses either alone or fully integrated into a bed, and includes powered pressure reducing mattresses either alternating pressure, low air loss or powered flotation without low air loss or an advanced pressure-reducing mattress that is non-powered.

- Category 3 includes air-fluidized beds. Category 3 is a specialty bed system that circulates filtered air through silicone coated ceramic beads. Accessories include positioning wedges and pillows, heel or elbow protectors and sheepskin pads.

These mattresses and specialized surfaces are indicated for immobile or bed-bound beneficiaries who need pressure reduction or relief to preserve skin integrity and/or facilitate wound healing.

Support surfaces for wheelchairs include back support, seat support, head support, lateral trunk supports, anterior trunk supports, lateral pelvic supports, medial knee supports, lateral knee supports, arm support, foot support, pelvic positioning straps, and any other support surface that is needed to assist the beneficiary in maintaining and/or improving posture, function, skin health, circulation, and respiration.

The supplier shall provide a certified wound care nurse to perform the initial delivery, set-up, beneficiary education, ongoing monitoring, and follow-up for support surfaces for beds.

The supplier shall provide qualified staff for the delivery/set-up, beneficiary education/training and follow-up services for support surfaces for wheelchairs.

Inspection and Preparation

Intake

See General Product-Specific Service Requirements

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Provide or coordinate provision of information and instruction to beneficiary and/or caregiver about prevention and/or management of pressure ulcers, including proper

positioning and turning, wound care, management of incontinence and moisture and importance of hydration and proper nutrition.

- Document whether the size and known durability of the bed appears to be appropriate relative to the beneficiary's approximate weight and height.
- Confirm that the bed frame properly supports the support surface system.
- Confirm that the bed is appropriate for the beneficiary's disability and limitations.
- Confirm that wheelchair supports are appropriate to the beneficiary's disability and limitations.
- Inform the treating physician of identified problems and recommendations for care.

Equipment Management

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Provide the support surface according to treating physician's order(s) and appropriate to the medical needs of the beneficiary, the care delivered, and the home setting;
- Air fluidized beds are not generally recommended for patients with pulmonary disease or unstable spines or for ambulatory individuals. Because so much air is needed to fluidize the total bed, dehydration (from water vapor escaping from the body) is a risk.
- The pressurized air in an air-fluidized bed is generally warmed to a temperature of 28 to 35 degrees Celsius. This warming feature could be beneficial or harmful, depending on specific patient characteristics. For example, the heat may be harmful to patients with multiple sclerosis or beneficial for patients in pain.
- Perform quality checks on support surfaces before delivery and at the beneficiary's home as per manufacturer guidelines.

Electrical Inspection for support surfaces for the bed

- Inspect all electrical components of support surfaces for damage or excessive wear (i.e. cracked or broken housings, or worn components).
- Check pendant, power, and mattress cords for chafing, cuts, or excessive wear.
- Ensure that all plugs are fully attached and free of damage.
- Check all functions with support surfaces including head raises and lowers properly, foot raises and lowers properly, bed ends raise and lower properly.

Delivery/Set-up

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Not provide mattresses, wheelchair cushions, or other support surfaces through a mail order service or through a distributor until after an initial face-to-face visit.
- Mount wheelchair support surfaces for optimal posture and comfort accommodating for range of motion limitations, muscular weakness, spasticity and skin integrity
- If air or fluid filled, ensure that it is filled appropriately for proper pressure distribution
- Ensure shape, size and placement accommodates needs of beneficiary.

Air fluidized bed

- In order to prevent bacterial contamination, the bed must be pressurized at all times.
- The sheet must be properly disinfected after use by each patient and at least once a week with long-term use.

Condition of the Home

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Assess beneficiary's home setting for safety concerns, e.g. power outlet and grounding needs for support surface, weight of bed system and apparent capacity of floor to support weight.

Condition of the Equipment

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Adjust all seating and positioning components to ensure optimal posture, comfort, and function.

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

Mattresses

- How to determine appropriate pressure distribution of support surface.
- What to do if support surface is damaged.

- If there is a power support surface system:
    - How to plug in system;
    - How to turn system on and off;
    - How to determine if support surface system is working properly;
    - What to do in case of power outage, including manual operation of system;
    - How to adjust pressure distribution and method to adjust parameters, if available;
    - Operation of battery back-up system, if available; and
    - Alarm system operation, if available.
- Life expectancy of support surface and how to determine if replacement needed.
- How to avoid potential entrapment.
- How to select and use sheets/coverings for custom support surfaces, if applicable.

Wheelchair Support Surfaces

- How to determine appropriate pressure distribution of support surface.
- Life expectancy of support surface and how to determine if replacement is needed.
- How to select coverings for custom support surfaces if applicable
- How to wash/clean support surface cover.
- How to remove and reposition the following components to ensure optimal posture, comfort and function:
    - Back Support;
    - Seat Support;
    - Headrest;
    - Lateral Trunk Supports;
    - Anterior Trunk Support;
    - Lateral Pelvic Support;
    - Medial Knee Support;
    - Lateral Knee Support;
    - Arm Support;
    - Foot Support; and
    - Pelvic Positioning Strap.

Safety Review

- Safe use of support surface system.
- Need to reposition beneficiary when using custom support surfaces.

- How to prevent damage to support surface.
- How to avoid potential entrapment.
- What to do in case of power outages or if power portions of support surface stop operating.
- How to minimize fire hazards, including flammability potential and toxicity of support surface.
- When and who to contact if support surfaces no longer meet the beneficiary's needs or the system requires modification.

Follow-up

See General Product-Specific Service Requirements

Appendix M: Walkers, Canes, and Crutches

This standard refers to beneficiaries using all styles of walkers (rigid, folding, wheeled, standard, with and without attachments such as seat attachment and crutch attachment), canes (quad or three prong, adjustable or fixed) and crutches (forearm and underarm, adjustable and fixed) in the home setting.

Inspection and Preparation

See General Product-Specific Service Requirements

Intake

See General Product-Specific Service Requirements

Service Plan

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Coordinate services with the treating physician in consultation with a physical therapist or occupational therapist as appropriate.

Equipment Management

See General Product-Specific Service Requirements

Walkers/Crutches/Canes

- Inspect for wear, tear, cracks, and rips of all tips and wheels.
- Repair or replace if worn or damaged.

Hand Grips and Arm Pads

- Inspect for wear, tear, cracks, and rips of all pads.
- Repair or replace if worn or damaged.

Folding System

- Ensure that the system can fold/unfold smoothly.

Brake System

- Ensure that brake system works properly.

Delivery/Setup

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Not deliver the initial delivery, set-up, and beneficiary education through mail order. For replacement items, the supplier shall provide these items with the exact specification as the beneficiary's initial treating physician's order through the mail-order service.

Condition of the Home

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Assess the beneficiary's home setting and evaluate for safety concerns related to use of walkers/crutches/canes; for example, stairs, width of doorways, doorway thresholds, placement of furniture, carpet pile, etc.

Condition of the Equipment

See General Product-Specific Service Requirements

Training/Instruction to Beneficiary and Caregiver(s)

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment in the following areas:

General

- How to use cane, crutches, or walker.
- How to use accessories on walkers.
- Need to check all grips, tips, pads, and wheels for excessive wear and replace on a regular basis.
- How to prevent injury to self by properly using device and accessories.
- Need to consult with physical or occupational therapist to determine optimal cane, crutch, or walker style.
- Need to consult with physical or occupational therapist for proper instruction in method to use cane, crutch, or walker.

All Styles Adjustable Walkers

- How to adjust height of leg extensions for proper height.
- How to adjust width of walker system if adjustable system.
- How to ensure that all adjustment buttons are engaged properly.
- How to adjust brake system and wheel system.

- How to adjust all accessories on walker including forearm attachment, pelvic support, IV pole, oxygen attachment, and specialty hooks.
- How to ensure that all accessory attachments are stabilized including seat, basket, tray, and pouch.
- How to fold walker, if folding style.
- How to use walker safely.

Wooden Canes

- Determine appropriate height and cut the cane.
- Cane should only be cut by qualified professional.

All Styles Adjustable Cane

- How to adjust height of cane for proper position and stability.
- How to ensure that all adjustment buttons are engaged properly.
- How to fold cane, if folding style.

Underarm Crutches

- How to adjust height of leg extension for proper position under arm.
- How to adjust position of handgrip for proper fit.
- How to ensure that all screws and bolts are tightened properly.

Forearm Crutches

- How to adjust height of leg extension for proper height.
- How to adjust forearm cuff position for comfort and stability.
- How to ensure that all adjustment buttons are engaged properly.

Follow-up

See General Product-Specific Service Requirements

Appendix N: Commodes

This standard refers to beneficiaries using commode(s) in the home setting. A commode is a portable toilet, not directly connected to central plumbing.

Inspection and Preparation

See General Product-Specific Service Requirements

Intake

See General Product-Specific Service Requirements

Service Plan

See General Product-Specific Service Requirements

Equipment Management

See General Product-Specific Service Requirements

Commode Options

- Commode chair, stationary, with fixed arms.
- Commode chair, mobile, with fixed arms.
- Commode chair, stationary, with detachable arms.
- Commode chair, mobile, with detachable arms.
- Commode chair extra wide and/or heavy duty, stationary or mobile, with or without arms (for beneficiaries weighing approximately 300 lbs or more).
- Commode chair with seat lift mechanism.

Delivery/Setup

In addition to the General Product-Specific Service Requirements, the supplier shall:

- Ensure that commode is suitable for the beneficiary's weight and height;
- Ensure that the bolts securing the rails are flush with the front cross bar (occasionally during shipping, the rails to the pail or pan dislodge);
- On models with adjustable height: ensure that the legs are secure and level before use.
- Adjust the beside commode to the proper height for the beneficiary;

- Set up the commode against a wall, close to the bed or chair where the beneficiary usually resides;
- For easy transfer, place the commode at approximately the same height as the bed;
- Place commode by the bed for use at night; make sure the brakes are on securely;
- The commode should be sturdy and should not slide easily;
- Adjust the level of the chair so that the beneficiary can easily transfer from the bed or chair to the commode;
- Equalize the leg height for all four legs of commode;
- Assist those with limited dexterity in proper selection; and
- Provide related supplies including disposable gloves and rubber accessories and grips.

Condition of the Home

See General Product-Specific Service Requirements

Condition of the Equipment

See General Product-Specific Service Requirements

Training/Instruction to Beneficiary/ Caregiver

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

Commode

- How to operate the commode.
- If commode has casters, lock wheels before use.
- How to clean.
- Need to ensure that the commode pail is in place, if not using the commode chair over a standard toilet.

Stationary Commode

- How to adjust height properly.
- If beneficiary's balance is poor, or it is difficult to get off the commode, a commode with backrest and arms may be needed.

Mobile Commode

- How to use a commode with wheels attached as a mobile chair to bring the beneficiary to the bathroom for a shower.
- Need to lock the wheels of the commode before use.
- Need to ensure that the container is under the seat.
- Need to put a small amount of water in the container before it is used.
- How to fasten seatbelt/safety strap, if available and needed for safety reasons.
- How to move the commode properly.

Detachable arms

- Drop-arm commodes have armrests that drop down out of the way to accommodate transfers in restricted or confined areas; arms will drop with a push of a button for unrestricted left-to-right leg movement.
- How to remove detachable arms to facilitate beneficiary transfers.
- How to slide onto the commode, using the upright arm for support.
- Need to return the arm to the upright position after transfer, and lock it securely (a click will indicate that the arm is in place).

Extra wide or heavy duty

- Offers additional strength and comfort with a larger seating area.

Seat Lift Mechanism

- Helps beneficiary gently seat and raise themselves, eases beneficiary gently into a seated position and automatically locks in place.
- How to stand by pressing down on the seat release lever and shifting forward.

Pail or pan

- How to install/remove the pail or pan.
- How to properly dispose of contents, clean, rinse, and replace container.
- How to remove the commode seat, lid, and pail from the chair frame for more thorough cleaning.
- Pail should be covered before moving it to prevent splashing or spilling.

- Replacement pails and toilet paper holders are available for most models.

Foot rest

- Attaches securely onto front frame legs.
- Adjustable foot rests that swing under chair, not out, for easier maneuvering in tight quarters.

Infection Control

- Need to thoroughly and frequently clean the commode using sanitizer.
- Need to wash and disinfect pail/pan after each use with soap and water.

Safety Review

The supplier shall instruct the beneficiary and/or caregiver to:

- Check all parts for signs of wear.
- Check all fasteners to ensure that they are tight.
- On height-adjustable models, check that the legs are securely locked and level before use.
- If the commode has casters, check that they are locked before using it.
- Check regularly that all screws are tight. If parts become loose or the chair wobbles, do not use the chair until it is repaired.
- Do not use the unit if there is any damage or missing parts.
- Follow all cleaning procedures.

Follow-up

See General Product-Specific Service Requirements

Appendix O: Bedpans and Urinals

This standard refers to beneficiaries using bedpans and urinals in the home setting. These products may be provided directly to the home, through a mail-order service or purchased in a store that sells medical device equipment and supplies.

Inspection/Preparation

See General Product-Specific Service Requirements

Intake

See General Product-Specific Service Requirements

Service Plan

See General Product-Specific Service Requirements

Equipment Management

See General Product-Specific Service Requirements

Delivery/Setup

See General Product-Specific Service Requirements

Condition of the Home

See General Product-Specific Service Requirements

Condition of the Equipment

See General Product-Specific Service Requirements

Training/Instruction to Beneficiary and Caregiver

In addition to the General Product-Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:

Bedpans and Urinals

- Provide equipment for home care that is reliable and easy for the intended beneficiary/lay caregivers to use (for example, urinal that is sturdy enough to withstand repeated use and will not readily crack or split to allow spillage of urine).

Bedpan

- A fracture bedpan (one with low, tapered front and convenient handles) is a flatter style that may be easier to manage for those who have trouble lifting their hips.

Urinal

- May be more convenient than a bedpan for males with limited mobility.

Related Medical Supplies

- Need supplies for observing Universal Precautions, including disposable gloves.

Sitz Baths

- Sitz bath hydrotherapy provides soothing relief from various conditions enabling beneficiary to soak hips and buttocks.

- Sitz bath equipment includes; portable sitz type bath used with or without a commode, tubing, solution bag, faucet attachments, chair, and related medical supplies.

- Ensure bedpan/basin proper size to fit standard home commodes.

Tubing

- Ensure that appropriate non-kink tubing to permit even flow.

- How to operate on/off valve that is attached to tubing, which anchors to bottom of bath bowl for controlled water flow.

- How to operate shutoff clamp.

Water/Solution Bag

- Solution bag may be hung above commode or set on top of tank.

Faucet Attachments

- Equipment may include cleansing cartridges, control handle, diverter valve, spray wand, hose, and faucet adapter kit.

Related Medical Supplies

- Saline Solution

Safety Review

- Some patients may become dizzy or experience rapid heart beat when standing up after sitting in hot water.

- It is best to have someone else present when doing a contrast sitz bath.

- Do not add bubble bath or oils.

- Replacement adapters available in either plastic or metal.

Follow-up

See General Product-Specific Service Requirements